

EVERY CATEGORY OF PROVIDER COMPARISON

BENEFITS, LIMITATIONS AND EXCLUSIONS						
CARRIERS	General Provisions/Rate Changes	ACUPUNCTURE	NATUROPATHIC	NUTRITIONAL COUNSELING	MASSAGE THERAPY	CHIROPRACTIC
Northwest Medical Bureau Fee for Service	Individual Rates not filed yet. Large rates unsure. Small rates increase \$1.77 PMPM excluding manipulations of spine as rates were available in 1999 riders.	Referral Needed: No Limitations: Benefits provided for medically necessary services with a limit of 12 visits per year. Exclusions: None	Referral Needed: No Limitations: No limitations in contract. Exclusions: Aromatherapy, biofeedback, educational therapy, milieu therapy, pain management, psychic surgery, and non-medical self-help training.	Referral Needed: No Limitations: Diabetic management training including nutritional therapy education. Benefit is limited to \$300 per calendar year. Exclusions: None	Referral Needed: No Limitations: Massage therapy services must be ordered by a physician. Limits are combined with physical therapy and occupational therapy. The combined limit is \$1,500 per year. Exclusions: None	Referral Needed: No Limitations: Medically necessary spinal manipulations are limited to 12 visits per year. Exclusions: None
Premiera Blue Cross Managed Care Plans	Rates not filed yet.	Referral Needed: Yes Limitations: For treatment of pain and for other therapeutic purposes: Has a \$10 copay. No limits on number of visits or dollar amounts Exclusions: None	Referral Needed: Yes Limitations: There is a \$10 copay. No limit on the number of visits or maximum dollar amount. Exclusions: None	Referral Needed: Yes Limitations: Benefits are limited to \$250 per member per year. Enrollee is responsible for %50% of allowable charges. Exclusions: Stress management classes, books or other educational supplies.	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: Benefits covers office visits, spinal manipulations and x-rays. \$10 copay. No limits on number of visits or dollar amounts. Exclusions: None

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Premiera Blue Cross Fee for Service	Rates not filed yet. Benefits are provided for services up to a maximum of \$500 per calendar year for acupuncture, naturopathic, nutritional and massage therapy when provided by a preferred provider.	Referral Needed: No Limitations: Services must be provided by a preferred provider, medically necessary to relieve pain, induce surgical anesthesia and therapeutic purposes. <u>Proposed language: 12 visits per calendar year.</u> <u>Effective date to be determined.</u>	Referral Needed: No Limitations: Benefits are provided for services of preventive and medically necessary care of a covered condition. <u>Proposed language: Benefits will be provided same as other physicians services.</u>	Referral Needed: Yes Limitations: Nutritional counseling and education directly related to a covered condition. Services must be provided by a certified dietitian/nutritionist. Diabetic counseling and education are separate from this. <u>Proposed language is the same.</u>	Referral Needed: Yes Limitations: Benefits are for medically necessary treatment of a covered condition. <u>Proposed language: 12 visits per calendar year under outpatient rehabilitative benefits.</u>	Referral Needed: No Limitations: Not limitations on the number of visits or dollar amounts. <u>Proposed language: 12 visits per calendar, effective date to be determined.</u>
PREMEA HEALTHPLUS Managed Care	Rates no filed yet	Referral Needed: Yes Limitations: Services must be performed by a participating provider. Exclusions: None	Referral Needed: Yes Limitations: Services must be provided by a participating provider Exclusions: None	Referral Needed: Yes Limitations: Diabetic education Exclusions: None	Referral Needed: Yes Limitations: Services must be provided by a participating provider and not otherwise excluded. Exclusions: None	Referral Needed: Yes/No Limitations: Spinal manipulations with PCP referral paid at 100%, self-referred is paid at 50% up to \$250 per year. Exclusions: None
Providence Health Care Managed Care Plan	Rates not filed yet. If medically necessary PCP may refer to participating alternative care provider.	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: Intradermal needles and Homeopaths.	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: Vitamins, dietary supplements and nonprescription drugs except as part of nutritional therapy for diabetes.	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: Services for non-neuromusculoskeletal disorders and physical therapy, except when associated with spinal manipulation.
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Regence Blue Shield Managed Care	Large group rates are not filed yet. Small group rates depend on prior existing benefit and network 0.27% to 2.12% PMPM. As agreed upon this language is effective 3/1/00.	Referral Needed: Yes Limitations: Limited to 12 visits per calendar year. Acupuncture for Chemical Dependency is a separate benefit. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: Outpatient diabetic self management training and education. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None
Regence Bluecross Blueshield of Oregon	Individual and Small group \$5.55 PMPM	Referral Needed: No Limitations: No limitations in contract. Exclusions: None	Referral Needed: No Limitations: No limitations in contract. Exclusions: None	Referral Needed: No Limitations: Nutritional counseling is covered for initial visit, plus two follow-up visits per condition Exclusions: None	Referral Needed: No Limitations: No limitations in contract. Exclusions: None	Referral Needed: No Limitations: No limitations in contract. Exclusions: None
Regencecare Managed Care	Large group rates are not filed yet. Small group rates depend on prior existing benefit and network 0.% to .25% PMPM. As agreed upon this language is effective 3/1/00. As agreed upon language is effective 3/1/00.	Referral Needed: Yes Limitations: Limited to 12 visits per calendar year. Acupuncture for Chemical Dependency is a separate benefit. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: Outpatient diabetic self management training and education. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None
Regence Northwest Fee for Service	Individual and large group rates not filed yet. Small group rates depend on prior existing benefit and network 0% to 4.23% PMPM. As agreed upon language is effective 3/1/00.	Referral Needed: Yes Limitations: Limited to 12 visits per calendar year. Acupuncture for Chemical Dependency is a separate benefit. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: No limitations in contract. Exclusions: None	Referral Needed: Yes Limitations: Maximum of 10 spinal manipulations per calendar year. Exclusions: None

Issues in Coverage for Complementary and Alternative Medicine Services:

Report of the Clinician Workgroup on the Integration of Complementary and Alternative Medicine

Executive Summary

This report documents the establishment and work of the Clinician Workgroup on the Integration of Complementary and Alternative Medicine (CWIC). This three-year process initiated by the Office of the Insurance Commissioner represents a constructive partnership between the public and private sector as well as health insurance carriers and providers. Participants included complementary and alternative medical health care providers, conventional medical providers employed in health insurance companies, primary care providers working in primary care organizations, educators of complementary and alternative medical students, and representatives of state regulatory agencies. One of CWIC's charges was to identify the many issues related to insurance coverage for services that may be considered "complementary and alternative" to "conventional" medical services. One of the most powerful outcomes from CWIC was the positive working relationships developed between the various participant communities. Some of the terms used in this report are specifically defined within the text, in footnotes, and/or appendices to clarify their usage. It is recognized that some terms may have other meanings that should not be extrapolated beyond the context intended here.

The Environment Preceding the Clinician Workgroup on the Integration of Complementary and Alternative Medicine - CWIC

In 1993, health care reform legislation was enacted by the Washington State Legislature that included provisions assuring consumers in Washington could buy health insurance even if they were sick or had changed jobs. Several provider groups pursued inclusion of all licensed providers in the state for insurance reimbursement of services within their respective practice scopes. To preserve the insurers' ability to select competent and efficient providers, the final legislation settled on the term every category, or type, of licensed provider being reimbursable, without mandating inclusion for every individual practitioner. Subsequent revisions to the law preserved these aspects of reform and the Office of the Insurance Commissioner (OIC) promulgated administrative rules to implement the legislative intent. Concurrent with and following court challenges, efforts were made by the OIC to pursue non-adversarial

processes to identify issues, barriers, and solutions for implementing legislatively mandated changes.

The first attempts at initiating these processes included discussions about coverage options for complementary and alternative medicine (CAM), services as well as how carriers would credential providers for their networks. These meetings were initially legally focused and were shifted to a more clinical direction after the agreement to include outside facilitation was made.

Formation of Workgroup - CWIC

The Office of the Insurance Commissioner's health policy staff and outside facilitators met with provider groups to identify those categories that would be most affected by this law. A series of informal discussions with health care practitioners helped identify those considered CAM, licensed by the Department of Health, and caring for patients with health conditions covered by the Washington State Basic Health Plan. Simultaneously, facilitators conducted face-to-face and telephone interviews with potential participants to further refine issues of interest and concern.

A representative group of payer medical directors and CAM providers was established using criteria that insured balance and emphasized provider experience. External independent facilitation was arranged and funded privately by the group participants themselves. In-kind

OIC staff resources were provided, but the majority of direct costs for this effort were borne by the carriers and providers themselves.

Health Insurance Carriers

- Aetna US HealthCare
- Community Health Plan
- Group Health Coop of Puget Sound
- Pacificare of Washington
- Premera Blue Cross
- Qual Med Washington Health Plans
- Regence BlueShield
- UnitedHealthcare

CAM Provider Associations

- Acupuncture Association of Washington
- American Massage Therapy Association, Washington Chapter
- Midwives Association of Washington State
- Washington Association of Naturopathic Physicians
- Washington State Chiropractic Association
- Washington State Dietetic Association

Physician Organizations

- Hall Health Primary Care Center
- Multicare
- Providence Health System
- Providence Seattle Medical Center
- University of Washington Physicians
- Valley Medical Center
- Virginia Mason Health Plans

Network Providers

- Alternare Health Services
- American Complementary Care Network
- American WholeHealth Network

Educational Institutions

- Ashmead College
- Bastyr University
- Brenneke School of Massage
- Brian Utting School of Massage
- Northwest Institute of Acupuncture and Oriental Medicine
- Renton Technical College
- Seattle Midwifery School

1998 CWIC Activities

An aggressive agenda was proposed to address coverage decisions, technology assessment, medical necessity, data collection and the gathering of literature on costs and practices, exploration of holistic¹ health care versus condition care, and integration of CAM services. A variety of approaches were used, including didactic presentations by outside experts or group participants, workshops and training, literature and survey research, group discussion, and/or facilitated decision-making. For obvious logistical and efficiency reasons, experts within Washington State were used.

1998 CWIC meeting topics included: Inventory of existing standards for CAM practices; status of coverage and use of CAM services by carriers and physician groups; carrier procedures for technology assessment, medical necessity determinations and coverage decisions; survey of CAM patients' views of perceived benefits;

clinical guideline training; CAM as add-on versus replacement to conventional care in high cost conditions; CAM integration into conventional delivery settings.

1999 CWIC Activities

The next full year of CWIC was directed at: Exploration of existing successful integrated CAM and conventional medical (CM) practices and development of draft clinical care pathways, algorithms, and protocols by participant CAM organizations; training of participant representatives in written clinical care pathway development; development of draft examples of clinical care pathways for conditions that the respective CAM providers might commonly address; identification of possible next steps for the group or future spin-offs; and research opportunities. Dedicated training was aimed at using evidence review as well as expert and community-based consensus development to draft written protocols in a way that non-CAM providers could apply within their respective professional communities.

1999 CWIC meetings topics included: Multidisciplinary clinic presentations; discussion on insurable practices; clinical care pathway and algorithm training; CAM practices survey project presentation; discussion on high cost conditions; research planning with University of Washington and Bastyr University

¹ Of or relating to wholism, emphasizing the importance of the whole and the interdependence of its parts. For the purposes of this report, the use of the word "holistic" should be considered to include health promotion, disease treatment and prevention, and wellness. The term does not fully reflect the range of differences in paradigms between CAM disciplines.

researchers interested in CAM; presentations from Bastyr University, University of Washington and CWIC participants; presentation of draft algorithms by participants; and summarizing of CWIC experience and review of material and information for the final report.

Variations in Coverage Strategies for CAM

There are currently several different coverage models for CAM services in use in Washington State. No preferred or "right" ways of including these benefits are being recommended by CWIC or OIC. Each approach has advantages and limitations for various constituencies.

- *Dollar Cap*: Applies maximum dollar expenditure per coverage year for a set range of CAM services.
- *Condition Based*: This CAM coverage model bases benefits on allowances related to specific clinical diagnoses or conditions. The covered benefit may require specific clinical regimens to have been followed prior to referral for CAM services.
- *Gatekeeper Method*: Characteristic of managed care coverage. Use of CAM requires direct referral from PCP gatekeeper, and benefits follow a medical necessity model. Some carriers include naturopathic physicians as PCPs.
- *Open Access Model*: Built on integration and coordination without a gatekeeper. This design allows a member to access network providers of all categories without the requirement of a PCP referral.
- *Self-referral and Preventive Care*: This model is usually structured as a rider to a core benefits package and usually follows a medical necessity model for coverage decisions. This could include patient access to a set number, or amount, of services without PCP referral, but require referral for additional coverage.
- *Discount Networks*: Some carriers have negotiated with CAM providers to provide discounts to their members, but do not provide reimbursement for the members' expenses for the services. This approach attempts to enhance access to CAM providers but does not reimburse for any of the services.

Lessons Learned

- Better understanding of each other's language and philosophies is needed.
- A forum of insurers and providers is a valuable environment for discussing coverage, payment and cost concerns.
- Creation of resources is needed for use in other like forums.
- Building trust and relationships breaks down barriers.

- The CWIC process increased awareness of the multifaceted nature of the current health care delivery system.
- Payers began to see the value in CAM delivery experience; providers gained understanding of managed care systems and payer issues.
- Practice guidelines have become integral in conventional medical delivery settings and assist payers in gauging medical necessity as well as appropriateness of care.
- CAM providers could benefit from broader application of quality improvement protocols to reduce variation and document improvement in patient progress and overall outcomes.
- Many of the changes in health care have resulted from marketplace factors that are frequently beyond the direct influence of providers, payers and regulators.

Next Steps

- Research should be a top priority. Specifically, cost data, claims experience, utilization appropriateness and other health services research issues will need to be better understood to assist in making coverage decisions.
- Care management considerations need to be explicitly addressed. Clinical guidelines and condition specific care pathways will assist CAM providers in conveying clinical rationale and the need for coverage determinations. Attention to these issues can also help CAM providers better understand their approaches and address practice variation.
- Education was an important by-product of the CWIC experience, and a forum to allow that to continue should be considered. CAM providers who can communicate well and can be made available should be identified.
- A collaborative forum for communication between payers, CM providers, CAM providers, and regulators should be established, perhaps at the national level.
- Integration of CAM and CM services was an ongoing theme throughout the CWIC process. Additionally, members felt that options and approaches for integration should be explored and inventoried.
- Delineation of care thresholds, financing mechanisms, and the quantification of cost-benefits for CAM and other preventative services will need to be prioritized.
- In general, sources of funding and resource support need to be identified for all of these activities.

Key Issues Regarding Integration

- *Relationship Development*: Mutual respect and recognition of perspectives is essential.

- **Speaking Different Languages:** Patience and openness is required regarding differences in training and experience, hence the syntax used for communicating each other's views and needs.
- **Learning Each Other's Paradigms:** Attitudes toward healing, intervention, care coordination may vary between CAM approaches and compared to CM approaches. Appreciation for how this impacts approaches to care is essential for coordination and integration.
- **Algorithms and Guidelines:** Recognition of these tools for both improving quality and outcome of care, along with communicating CAM care decisions and thresholds is important. Documentation of recognized limitations and strategies for preventing inappropriate use are essential.
- **Research Support:** The absence of research in support of a particular intervention's effectiveness should not by default be treated as though there was scientific evidence demonstrating ineffectiveness.
- **Members May Have Different Needs:** Each constituent, payer, CAM provider, CM provider and regulator has different perspectives, needs and accountable bodies that must be recognized. A forum for constructive engagement and problem solving is essential.

Recommendations of CWIC the for Integration of CAM

- Individual CAM professions should work closely with carriers to assist them in knowing when to cover their services for a specific condition, and to provide clinical algorithms to assist in supporting the claim.
- Insurers should involve the respective CAM professions when establishing CAM benefits packages.
- Participants in CWIC and their organizations should explore ways to maintain an informal network and consider seeking broader, perhaps national support for establishing an ongoing forum for dialogue and problem-solving.
- Educational strategies should be adopted for enhancing cross-fertilization and understanding of the issues of payers, CAM providers and conventional providers. Recognition of areas of mutual interest should be made explicit, and areas of divergent needs and priorities should be acknowledged and engaged constructively.
- Explore opportunities to use technology and communication to keep members aware of various methods to integrate CAM and CM.

**White House Commission on
Complementary and Alternative Medicine Policy**

**Washington DC
December 4-5, 2000**

Access and Delivery of CAM Services

In addressing you today about the access and delivery of CAM services, I want to give you some background about how Washington's "every category of provider" law is being implemented, due to the many misunderstandings.

While the law has taken great criticisms, it is important to note that it is one of the few sections of Washington's 1993 Health Care Reform Act that was NOT repealed. It was the most controversial and most popular reform – and ultimately was let stand by the US Supreme Court.

This law has taken into account the attempt of managed health care to save money as well as giving patients some access to choice and involvement in their health care options.

In Washington, 6 of the CAM professions are regulated by the Department of Health under licensure or certification (Acupuncture, Chiropractic, Dieticians, Massage Therapy, Licensed Midwives, and Naturopathic Physicians). Their regulatory scope of practice must permit

the provider to treat the condition presented. Patients must already have benefits covering a condition that is within the scope of practice of the chosen provider, and with respect to managed care, the provider must be *contracted* with the carrier or their designated network to be eligible for reimbursement.

This is not an “any willing provider” law, nor is it a mandated benefit law. It allows consumers a choice of the provider who will treat the condition for which they seek care.

There are currently several different coverage models for CAM services used in Washington. Neither the OIC nor any of its collaborative work groups have recommended a “right way” of including these benefits. Each approach has advantages and limitations for various constituencies.

***The Dollar-Cap* method is a straightforward benefit that generally applies a maximum dollar amount allowed in a given coverage year for a set range of CAM services. Acupuncture, massage therapy and naturopathic medicine are the most commonly included services under this model. CAM benefits may require a referral from a primary care provider and patients must pay necessary co-pays and deductibles. When the limit has been placed on more than one profession, or “all of CAM services,” then the OIC would deny approval of that benefit limit.**

The Condition Based model bases benefits on allowances related to specific clinical diagnoses or conditions, such as the use of acupuncture for pain, or naturopathic care for migraine headache. The covered benefit may require specific clinical regimens to have been followed prior to referral for CAM services. An example is requiring physical therapy prior to authorizing massage therapy. The condition-based approach usually requires a PCP referral and requires co-payments and deductibles.

The Gatekeeper Method is frequently employed under managed care strategies. A unique difference with this model is that in some cases the naturopathic physician is eligible to function as a Primary Care Physician. Patients seeking CAM services to be covered under their insurance benefits need to have a referral from their PCP, whether the PCP is an ND, MD, DO, or ARNP. The benefits are subject to medical necessity requirements established by the insurer, but may be determined by the at-risk PCP group as well.

The Open Access Model is built on a strong care coordination and quality infrastructure allowing integration of CAM and CM practitioners and their services. Enrollees are allowed to access network providers of all categories without a PCP referral. In fact, there is no PCP or “gatekeeper” required.

The Self-Referral Method allows patients to directly access ALL providers, and Preventive Care Services are usually a separate rider. Although the self-referral approach method does not usually require a PCP referral, benefits are subject to medical necessity determinations.

Frequently the self-referral approach may be implemented in conjunction with a preventive care benefit. Preventive care benefits are not usually part of the policy, but can be negotiated by a purchaser.

Discount Networks: Some insurers have begun to negotiate discounts with CAM providers for their policyholders in exchange for being listed in the carriers' approved provider guide. These carriers do not provide reimbursement for the enrollees expenses and costs are paid by the patient. This is not in compliance with our statute and rules related to the "every category of provider" law, since the patient doesn't actually engage their benefits when seeking care from CAM providers.

Relating back to the law once again, carriers have the right to credential providers as long as the standards are consistent with those established by the Department of Health. Carriers must set network adequacy requirements based on the number of covered lives in a jurisdiction where they are responsible for providing benefits.

Carriers have the right to set the coverage limits, including services of CAM providers. The OIC rules state these limits may not be

unreasonable and may not be set by provider type, but can be set by covered services. And the carrier can't exclude a particular category of provider altogether, nor can it cover certain provider types only by a separately priced optional benefit.

"Reasonable limits" has yet to be defined, and the filed limits by each of the carriers is something currently under review. A "datacall" related to criteria used by insurers to establish limits for health care services is currently underway by our office. After a preliminary review of this data I can tell you there is NO established pattern of how these insurers set limits on care. In text, I have provided you some of those preliminary results.

Additionally, we have asked each carrier to identify at what point they require outside, or paper review, of services, and if there are protocols available that provide guidance on limits to these services. Predominantly, internal guidelines are set, some with outside input, and some without.

When carriers are using providers to perform reviews, there does not appear to be a pattern emerging as to which profession is used most often or to what degree.

When asked about specific condition limits, there did appear to be a strong pattern of set limits on rehabilitation, chemical dependency, mental health, preventive care, and hospital-based services.

Most carriers are not using CAM providers during medical review, unless the carrier has contracted with a CAM provider network that employs their use for medical review. When asked if carriers are using provider advisory panels, and for which professions, the responses are predominantly affirmative for conventional providers, but for CAM providers it is mostly if the carrier uses a contracted network. Consequently, when carriers contract with outside entities to provide these panels, there seems to be a disconnect to the very concept of integrated medicine.

To close, I will reference a chart I submitted in advance, outlining the “reported” coverage that insurers in Washington state indicate is available to their enrollees. I would like to point out that there is conflicting information from many of the carriers regarding what they file as a benefits, what the cost of the benefit is to them or their purchaser, and what they report in policy inquiries as to how they manage the benefit.

It is the goal of the Office of the Insurance Commissioner to bring all of these pieces of information together for consistency. It is also our goal to assure that insurers are following the law that consumers worked to hard to pass, and maintain. And finally, it is our goal to make sure that consumers get what they pay for in their health care benefits.

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Introduction – Ayurveda and Vedic Medicine

Vedic medicine is reported to be the oldest continuously practiced medical system, having its origin in the ancient Vedic civilization of India. Vedic medicine, including Ayurveda, has been recognized by the World Health Organization and other authorities as a sophisticated system of natural medicine with a detailed scientific literature comprising classical medical texts, an uninterrupted oral tradition predating the written texts and a comprehensive range of clinical procedures for the prevention and treatment of acute and chronic diseases. Maharishi Vedic Medicine is a modern restoration of ancient Vedic medicine in a scientific context, taking into account the complete range of diagnostic and therapeutic approaches in accordance with classical texts. This holistic approach encompasses 40 main branches dealing with mental, physical, behavioral, and environmental influences on health.

I. Describe data on clinical effectiveness, cost effectiveness, or patient satisfaction. For which conditions and for whom was Ayurveda most effective?

Over the past 30 years, more than 600 published randomized controlled trials, other controlled clinical studies, and laboratory investigations have evaluated modalities of traditional Vedic medicine for efficacy, clinical effectiveness, safety, mechanisms, and cost effectiveness. Data on both individual component and comprehensive systems approaches of Vedic medicine are briefly reviewed below.

A. CLINICAL EFFECTIVENESS

1. Transcendental Meditation [TM] program

Comparative Studies: Recently, a review of studies on stress reduction techniques including 13 meditation and relaxation techniques reported that ten meta-analyses covering a total of 475 studies showed a wide range of effect sizes (i.e., nine fold difference) among these techniques in reducing sympathetic activation, anxiety, substance abuse, and in improving psychological well-being (Orme-Johnson and Walton, 1998). The review reported that after controlling for expectation, duration of practice, experimental bias, strength of experimental design and other factors, the Transcendental Meditation technique, with its basis in the Vedic tradition, was substantially more effective on a broader range of health outcomes than other clinically derived or traditional approaches.

Cardiovascular Disease: Over the past decade, a series of randomized controlled trials supported by the National Institutes of Health and other controlled studies have focused on the effectiveness of the TM program in the prevention and treatment of cardiovascular disease (CVD) in high risk minorities and aging populations. In terms of primary prevention of CVD, these studies have demonstrated that TM was effective in reducing several cardiovascular risk factors, i.e., hypertension, smoking, alcohol abuse, anxiety, and oxidized lipids. In the case of hypertension, the effects were similar in magnitude to antihypertensive drug therapy.

Recent studies on the secondary prevention of atherosclerotic cardiovascular disease have demonstrated reductions in myocardial ischemia, regression of atherosclerosis, improvements in Syndrome X, 80% lower rates of CVD morbidity, and 50% lower risks of mortality from CVD and all-causes. Proposed basic mechanisms for these clinical effects appear to be part of an integrated set of endogenous self-repair and homeostatic mechanisms that is stimulated by this Vedic medical practice.

Other clinical conditions: Published clinical research suggests that TM may be useful in the treatment of several noncardiovascular chronic disorders including asthma, insomnia, anxiety, depression, post-traumatic stress disorder, substance abuse, and in the prevention or reversal of age-related declines in cognitive function, mood, and psychomotor coordination and quality of life. Preliminary data in cancer populations suggest improvements in quality of life and reductions in mortality rate.

2. Physiological Approaches of Vedic Medicine

Herbal Preparations: There is an extensive experimental literature on Vedic medicine herbal preparations. Animal and in vitro studies indicate potent antioxidant, anti-carcinogenic anti-atherosclerotic effects when compared to conventional control compounds. One preparation widely used in the West, called Maharishi Amrit Kalash, has shown antioxidant potencies 1000 times greater than conventional antioxidants such as vitamins C and E. Human studies have shown prevention of toxicity from cancer chemotherapy, improvements in diabetes mellitus, and other chronic disorders recalcitrant to treatment by modern medicine.

Physiological purification procedures: Studies on traditional physiological purification procedures of Maharishi Vedic Medicine have shown improvements in well-being, energy-vitality, strength-stamina, appetite and anxiety, depression, fatigue, and cardiovascular risk factors.

3. Vedic Sound and Vedic Vibration Technologies

Recent randomized, double blind, placebo-controlled trials have reported that the application of vibration therapy based on the sounds of the Vedic literature were associated with rapid improvements in symptoms of chronic arthritis, pain, and other disorders in a significant percentage of patients resistant to other treatments.

4. Near Environment Health

Maharishi Vedic Medicine also incorporates the knowledge of Vedic architecture or Sthapatya-Veda. Recent controlled research indicates reduced disease rates and improved well-being in individuals living in building designed according to these classical principles of healthy architecture.

5. Distant Environmental Health

Knowledge of chronobiological rhythms correlated with cyclical movements of the sun, moon, stars, and planets is considered in the comprehensive approach of Maharishi Vedic medicine. Clinical experience with these technologies suggests a high degree of predictive and ability and intervention targeting not otherwise attainable with conventional diagnostic or therapeutic modalities.

6. Vedic Approach to Public Health

Numerous observational and experimental studies have suggested that practice of Transcendental Meditation and its advanced program (the TM-Sidhi program) in groups has beneficial effects on health patterns in the community, including reduced violent behavior and hospital admissions.

7. Multimodality Maharishi Vedic Medicine

Recent publications report that the practice of Maharishi Vedic Medicine as an intact system incorporating at least several of the modalities highlighted above is associated with clinical improvements in several chronic disorders, including diabetes, Parkinson's disease, sarcoidosis, secondary hypertension, asthma, chronic bronchitis, rheumatoid arthritis, eczema, constipation, and headaches.

B. COST EFFECTIVENESS

The TM program has been shown to reduce two indicators of health care expenses: insurance claims, and payments to physicians. In a cohort study of 2000 TM practitioners compared to 600,000 controls, it was found that the meditation group had 53% fewer hospital admissions and 44% fewer outpatient visits. The largest reduction (87%) was for heart disease. Two well-designed observational studies in Quebec found that payments to physicians were reduced by approximately 80% over 6 years in TM practitioners.

In an economic model of the costs of long-term treatment of hypertension with conventional drugs compared to TM, it was found that the costs of the nonpharmacologic therapy with meditation were significantly less than treatment with the least expensive antihypertensive drugs.

The practice of Maharishi Vedic Medicine as a comprehensive system of health care was associated with four-year total medical expenditures per person 57-59% lower than controls for all age groups, and major disease categories. The greatest savings were for Vedic medicine subjects over 45 years old who had 88% fewer total patient days than controls.

C. PATIENT SATISFACTION

Compliance with regular practice of the TM program has been surprisingly high, varying from 70% to 97% across randomized clinical trials in diverse populations including lower socioeconomic African Americans, the elderly, adolescent African Americans as well majority study populations. This contrasts with prescriptions for antihypertensive medications, which average 33-50% compliance. International studies have shown high rates of acceptability of the TM program and other modalities of Vedic medicine in approximately 100 countries around the world.

In summary, these and other scientific data indicate that the treatment and prevention of the following conditions with Vedic medicine is indicated: a. Risk factors for cardiovascular disease, including-hypertension, smoking, alcohol and drug abuse, psychosocial stress, hyperlipidemia-especially oxidized lipids; secondary prevention of

coronary heart disease and stroke; tertiary prevention of CVD – rehabilitation of post-MI or post-coronary revascularization patients, b. Cancer- enhancement of quality of life, possible reduction in mortality rates, prevention of chemotherapy toxicity; c. Psychological disorders--anxiety, depression, post-traumatic stress disorder; d. Substance abuse disorders; e. Diabetes mellitus; f. Aging – health promotion and disease prevention in the elderly; g. Menopause – women’s health--menopausal symptoms ,osteoporosis. Common syndromes in primary care practice--chronic pain, arthritis, insomnia, functional digestive disorders, and constipation.

II. Who should provide these products and practices?

Practitioners: Currently, Vedic Medicine is practiced by physicians and other licensed modern health professionals who have received specialized training in Vedic medicine as part of their continuing education. In addition, trained Vedic professionals with either a bachelors degree, PhD degree, or certificate from the College of Maharishi Vedic Medicine (at Maharishi University of Management) in Iowa or Maharishi College of Vedic Medicine in Albuquerque, NM or unaccredited Ayurvedic schools in the US practice may practice either as consultants to licensed physicians or as unlicensed independent practitioners.

The following categories of practitioners are recommended to provide these services in the future: Conventional practitioners with additional training in Vedic medicine: e.g., MDs, Osteopaths, Chiropractors, Nurse clinicians and Vedic medicine specialist practitioners. Training is to be provided at both BA and PhD levels as consultants to physicians and as independent practitioners

Certification and licensure: We recommend that the federal government encourage or legislate a two-stage certification and licensure process in all states for Vedic medicine practice. That is, for the immediate term, i.e. for at least the next five years, all states follow a Minnesota-type model. In this scenario, CAM practitioners who are practicing an approved form of natural medicine and who have been certified by a national organization in their specialty be allowed to practice clinically. Furthermore, we recommend that the federal government either encourage or mandate that all states adopt licensing procedures for natural medicine professionals. These procedure would include, among other points, that licensure require successful completion of a predefined level of education through an approved educational institution and certification by a national professional practice organization in the field.

Product accessibility: General products may be available over the counter. More specialized and more potent products may be better available only on the recommendation of a certified practitioner

III. Should Ayurveda be accessed and delivered as a stand-alone system or should it be integrated with conventional medicine and why?

We recommend both approaches simultaneously. This would include a specialized Vedic medical center for each community or congressional district and integration of specially trained practitioners within conventional health care delivery systems. The specialized centers would allow provision of modalities that would be less feasible within conventional medical settings currently.

IV. What policy recommendations do you have for the Commission?

Reimbursement criteria: Vedic medicine professional services and prescribed products should be reimbursed by third party payers [e.g., Medicare, Medicaid, as well as indemnity insurance, prepaid health plans] if they have been shown to be effective by controlled clinical research published in peer-reviewed scientific journals. Also, we recommend that preventive measures be reimbursed in addition to treatment approaches.

Licensure: see above

Education: We recommend that the federal government make available grant support on a competitive basis for institutions of higher learning to provide education and training for clinical practitioners of Vedic medicine.

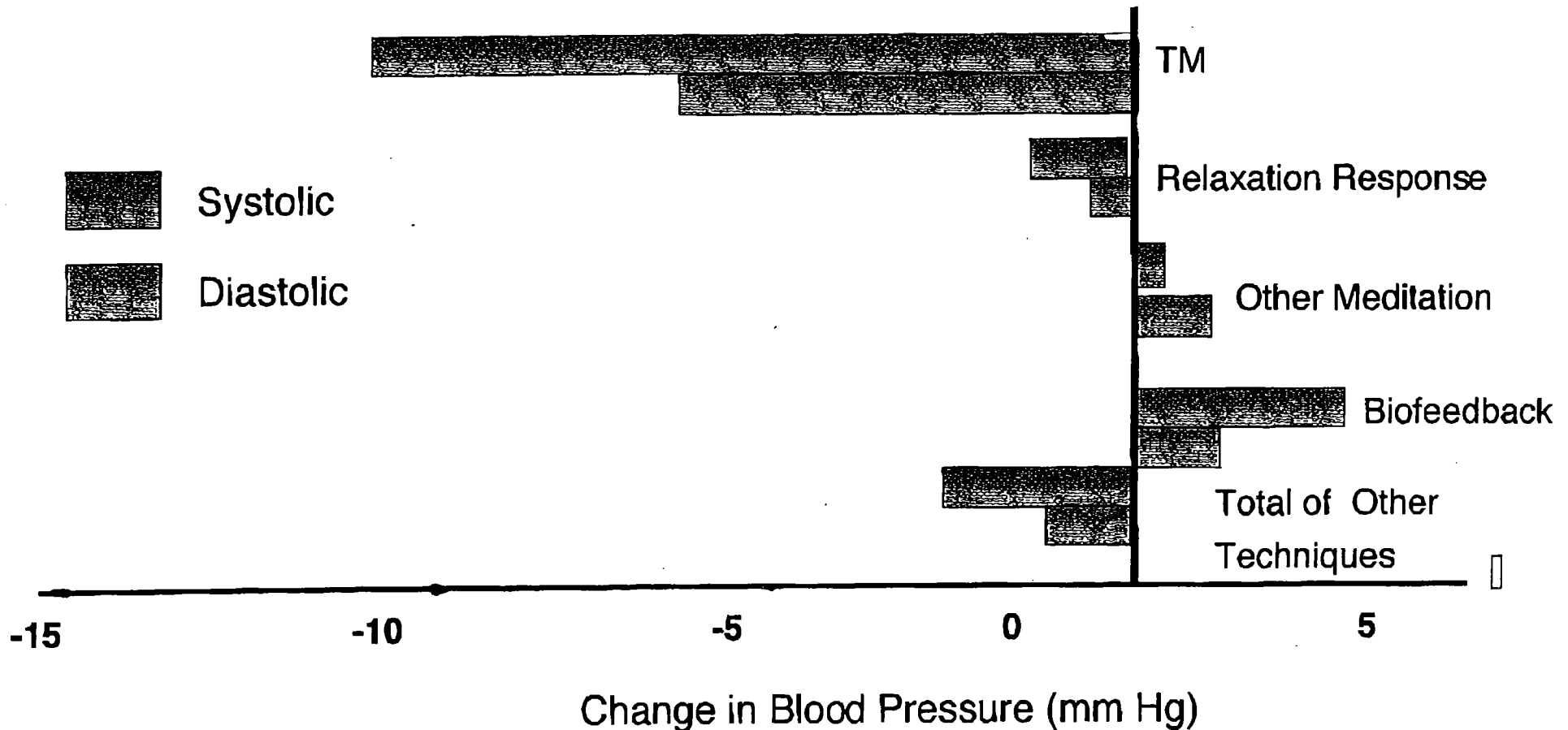
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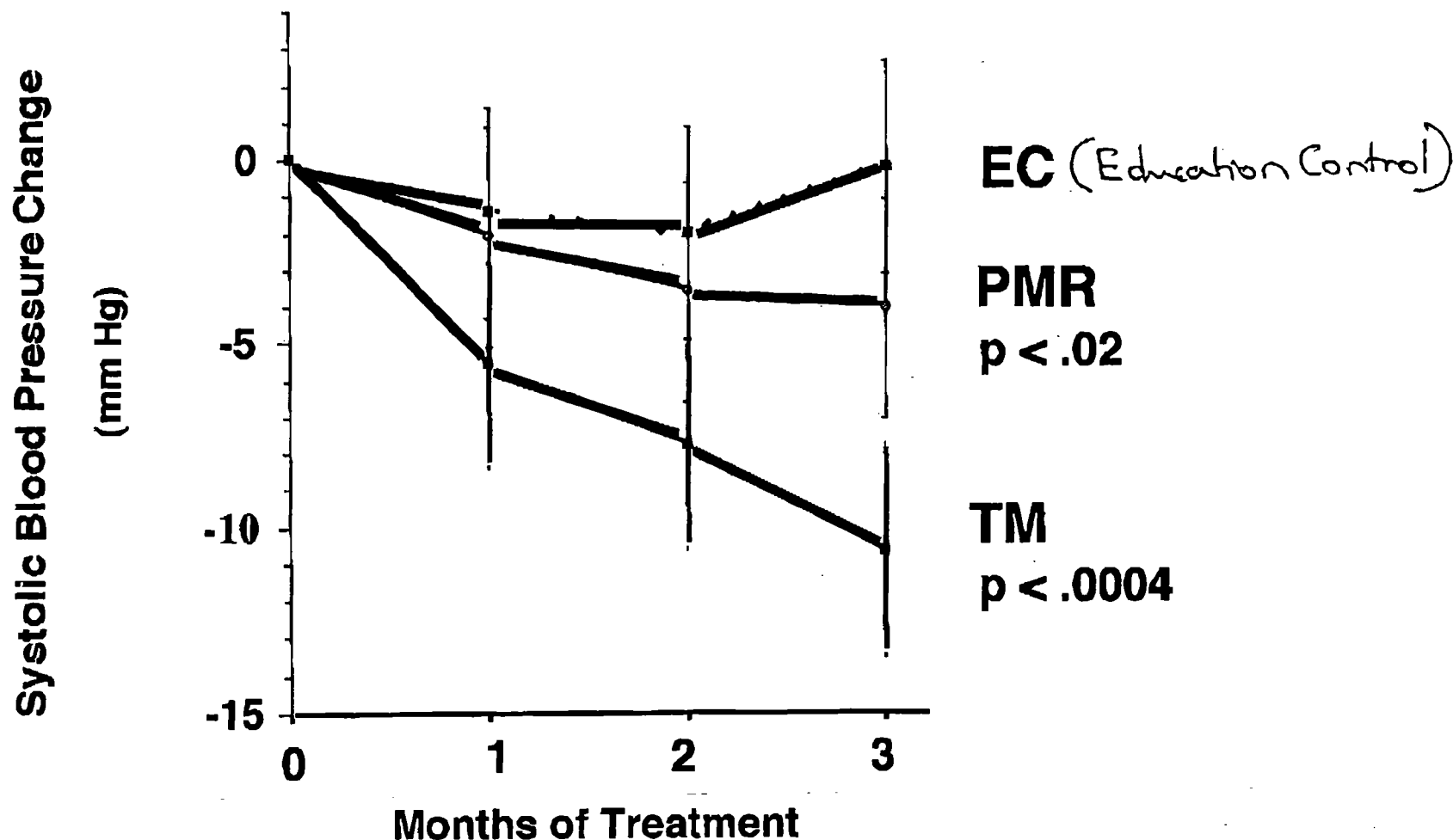
Effectiveness in Reducing Blood Pressure

Meta-analysis of 28 studies

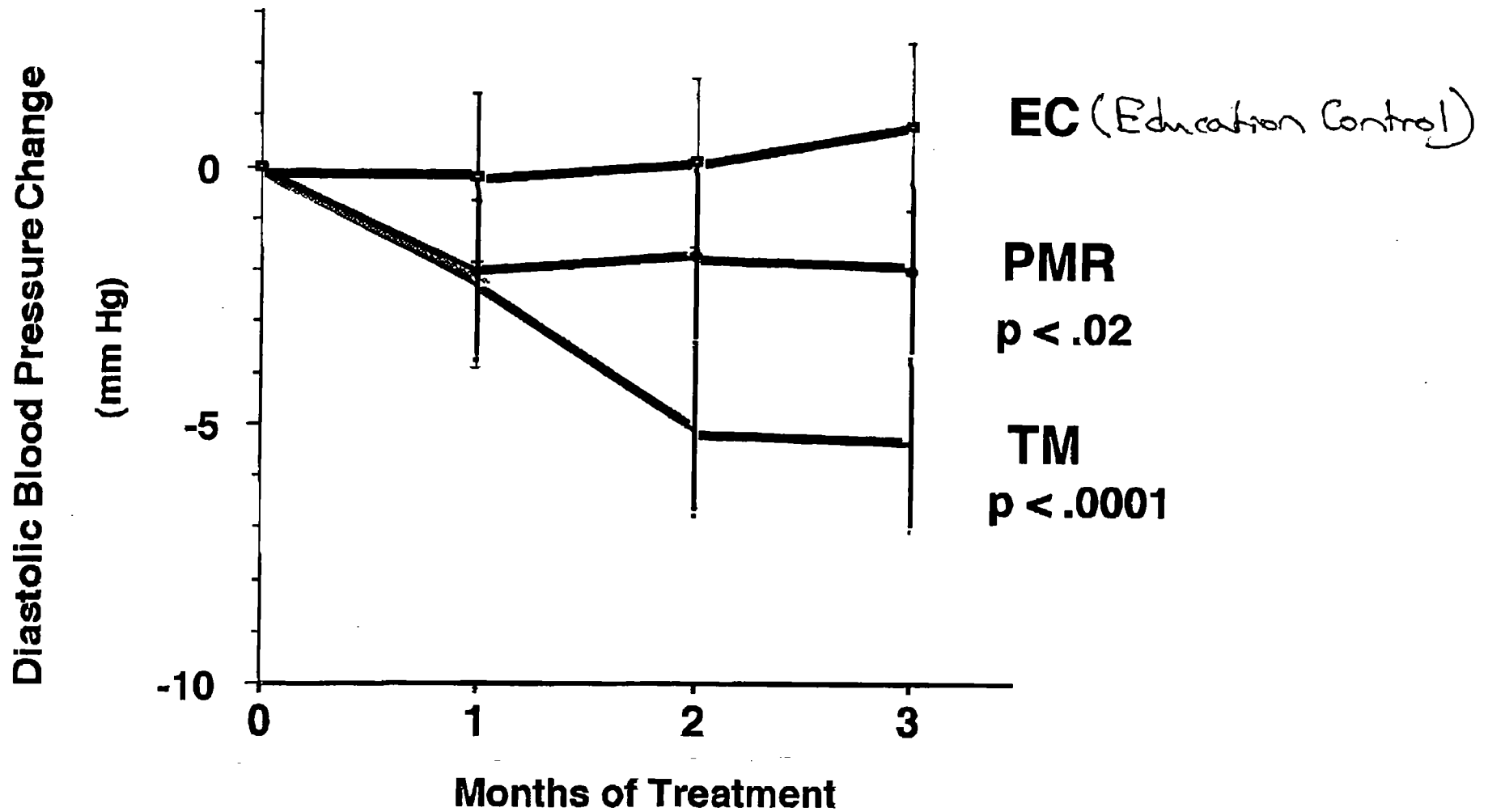


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- 2) Orme-Johnson DW, Walton KG : *American Journal of Health Promotion*, 12 [5]:297-298, 1998

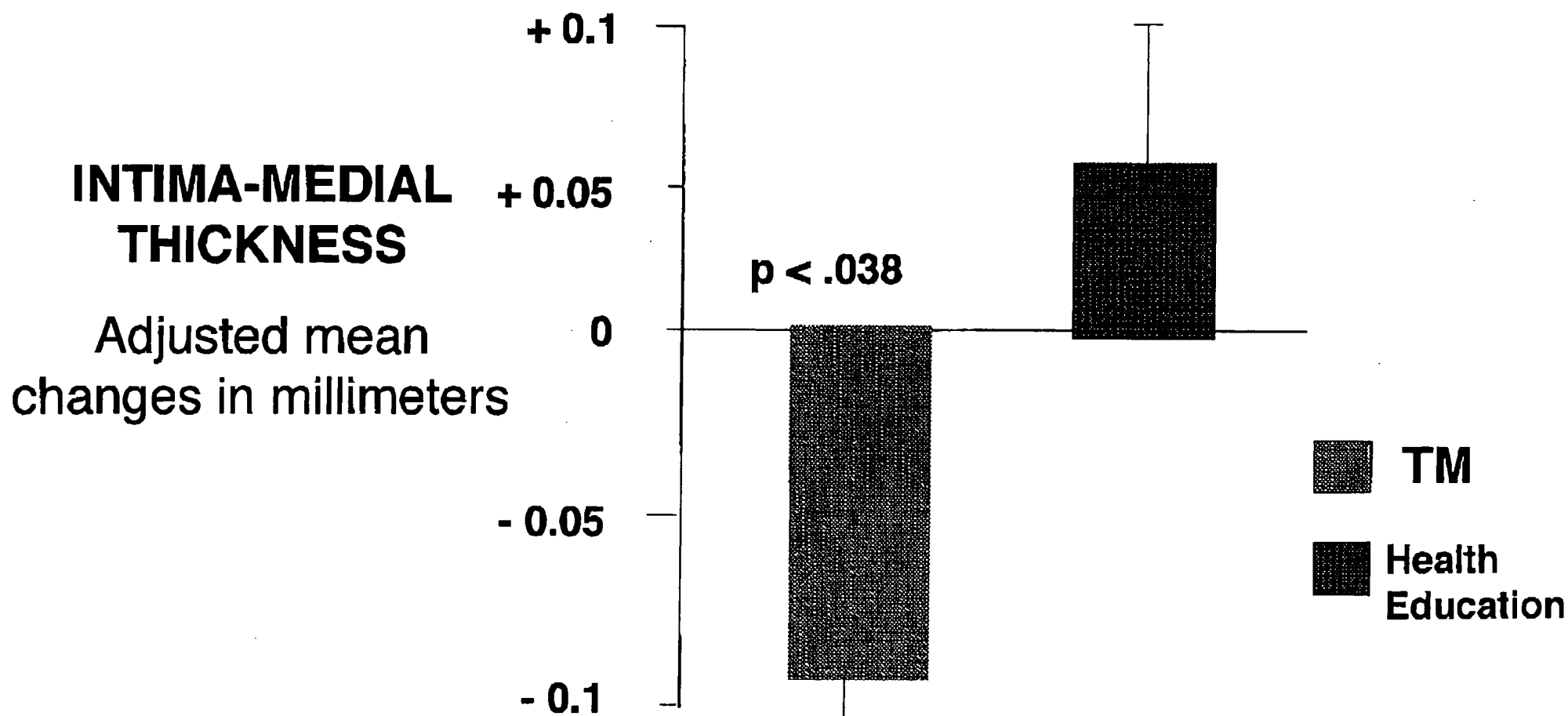
Changes in systolic blood pressure in older African Americans after three months: Transcendental Meditation vs. Progressive Muscle Relaxation



Changes in diastolic blood pressure in older African Americans after three months: Transcendental Meditation vs. Progressive Muscle Relaxation



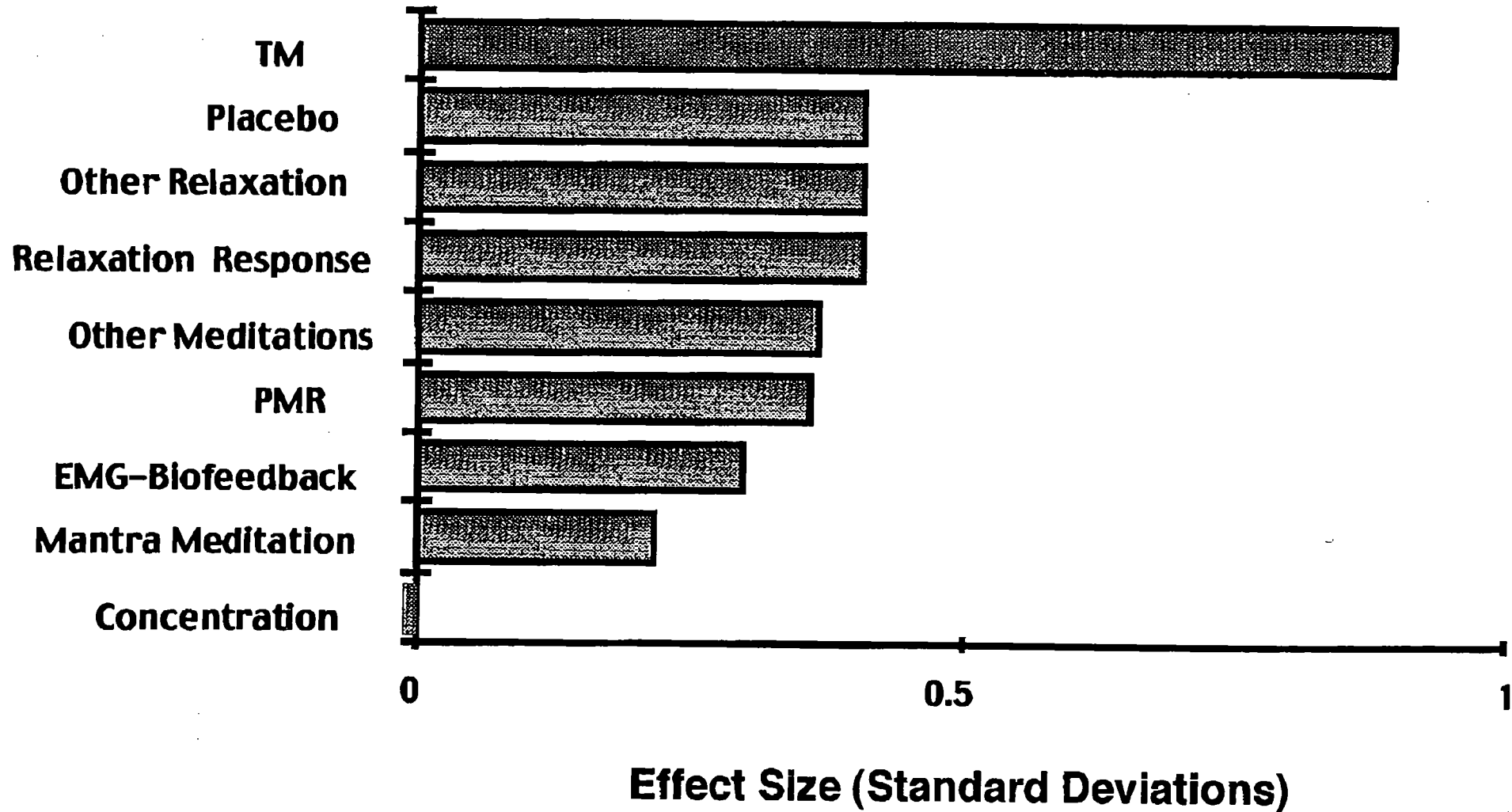
Effects of Stress Reduction on Carotid Atherosclerosis



Castillo-Richmond AB, Schneider RH, et al. Effects of Stress Reduction on Carotid Atherosclerosis in Hypertensive African Americans. *Stroke*, 2000; 31; 568-573

Effectiveness in Reducing Trait Anxiety

Meta-analysis of 146 studies

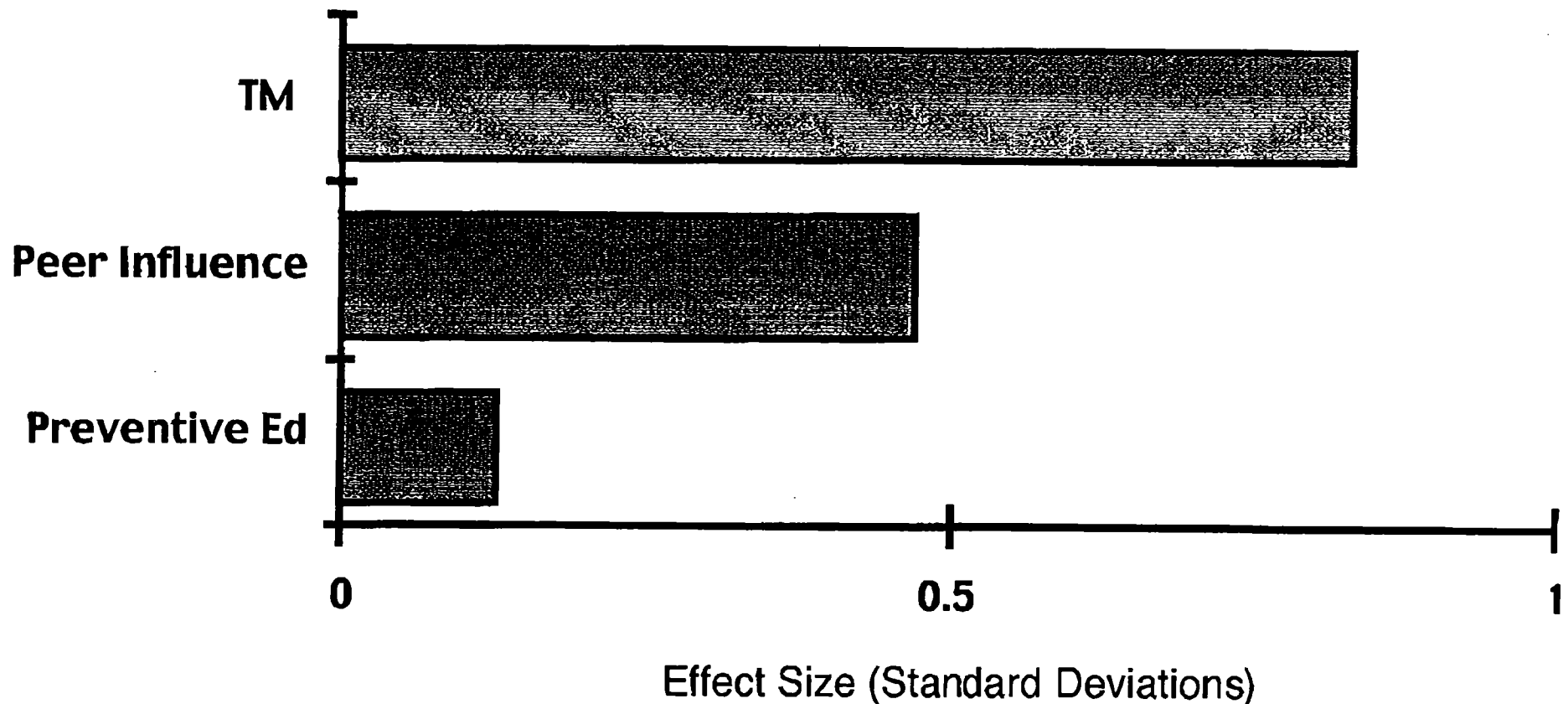


Eppley KR, Abrams A, Shear J: *Journal of Clinical Psychology*, 45;957-974, 1989

Orme-Johnson DW, Walton KG: *American Journal of Health Promotion*, 12 [5]:297-298, 1998

Effectiveness in Decreasing Drug Abuse

Meta-analysis of 70 studies

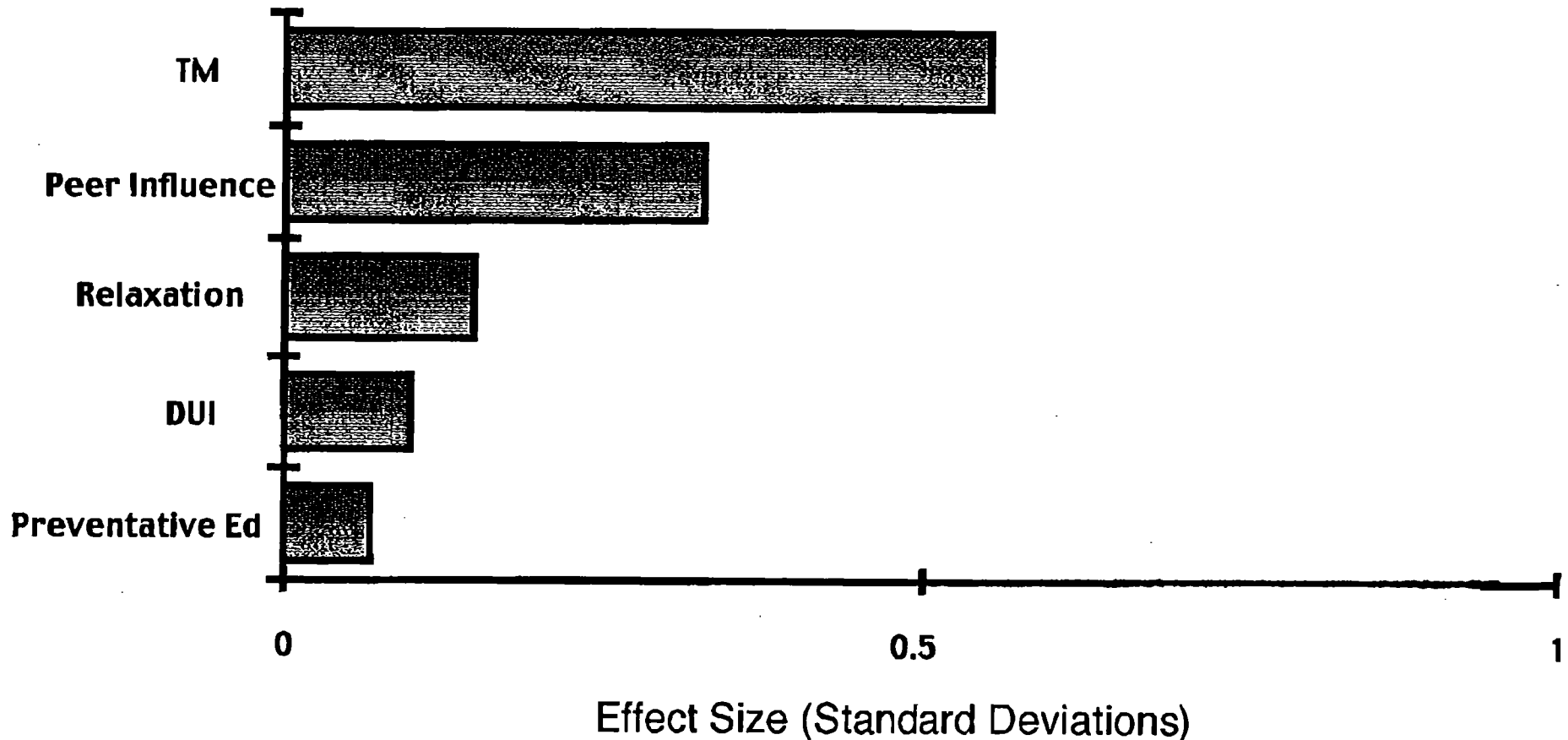


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2) Orme-Johnson DW, Walton K: *American Journal of Health Promotion*, 12 [5]:297-298, 1998

Effectiveness in Decreasing Alcohol Use

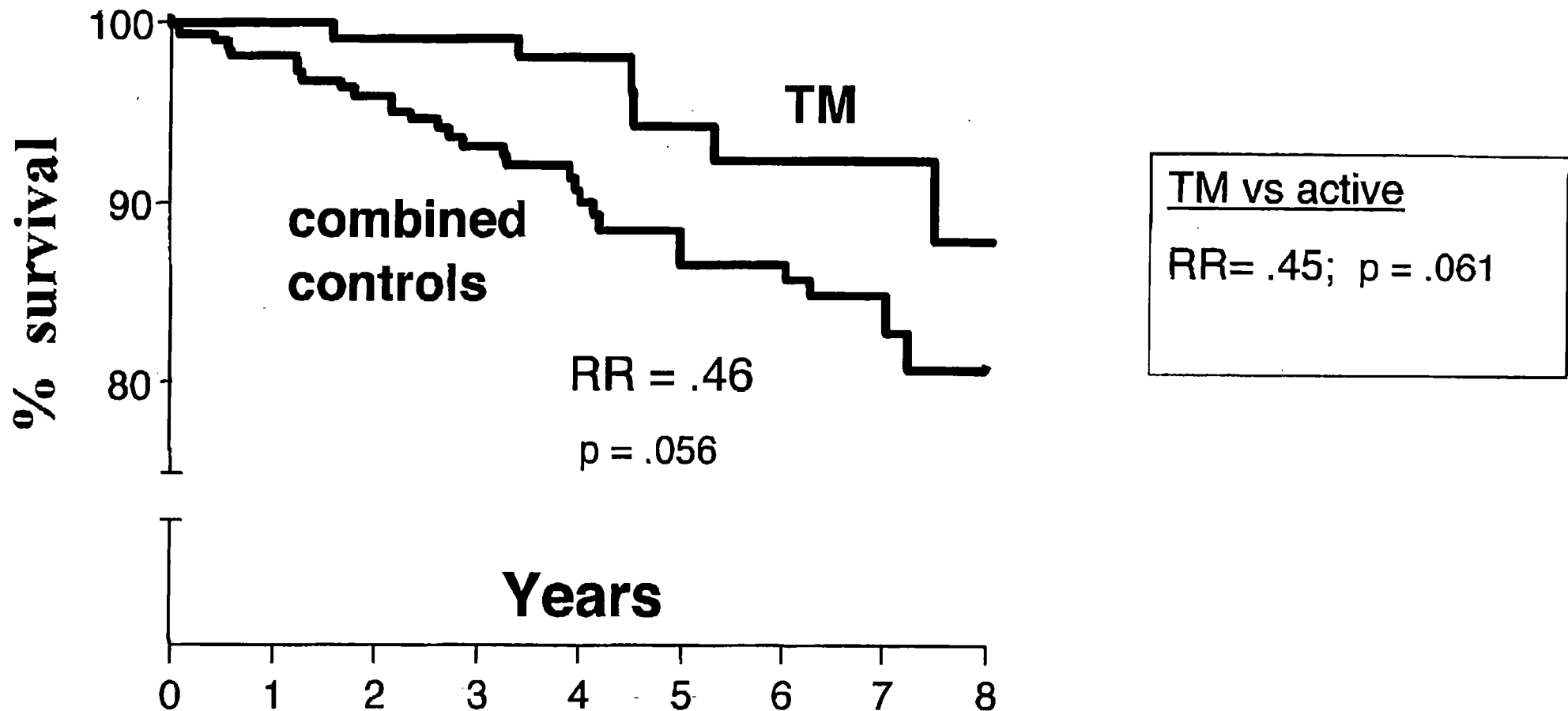
Meta-analysis of 97 studies



1) Alexander CN, Robinson P, Rainforth MV, *Alcohol Treatment Quarterly*, 11: 13-87, 1994

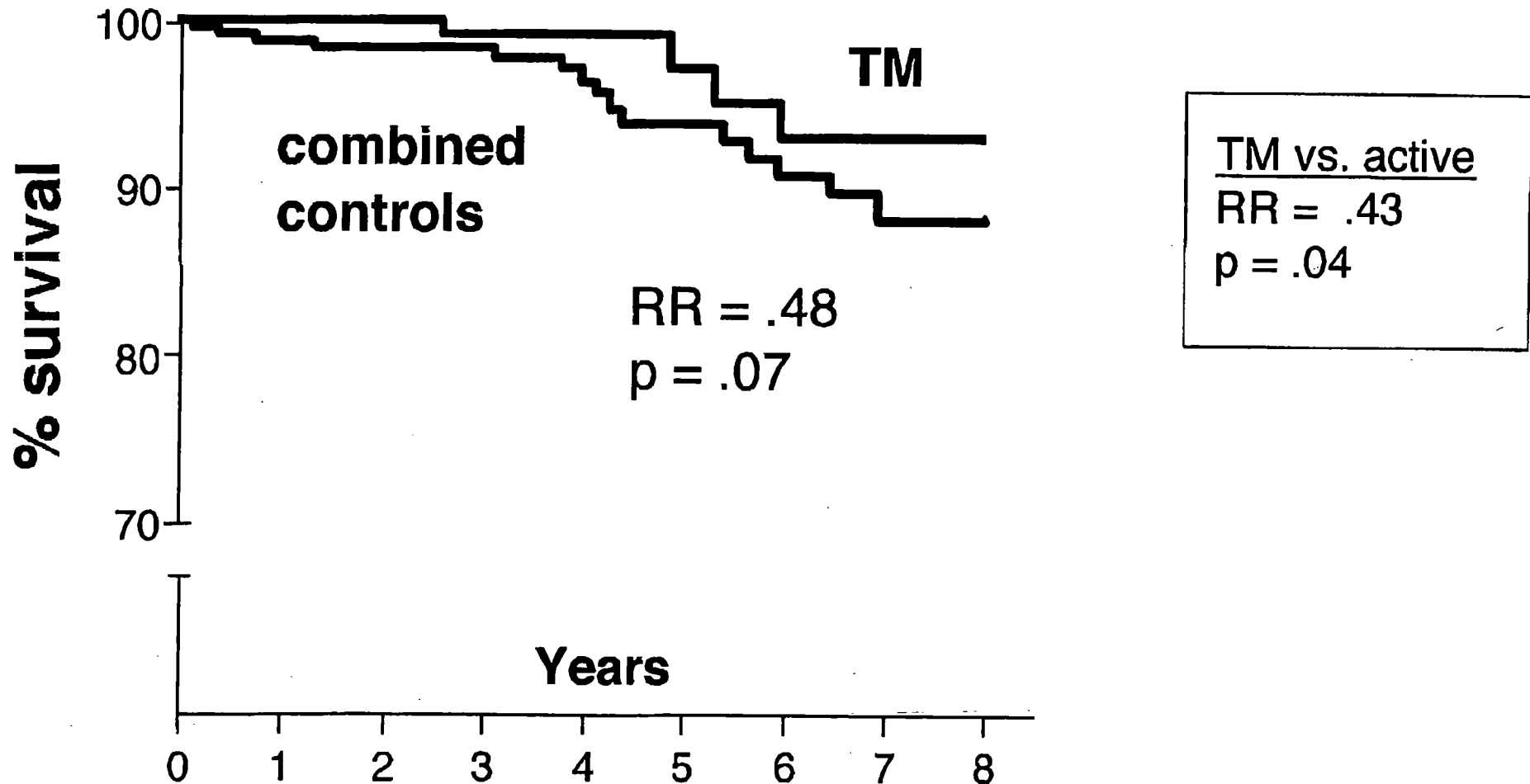
2) Orme-Johnson DW, Walton K: *American Journal of Health Promotion*, 12 [5]:297-298, 1998

Cardiovascular Mortality



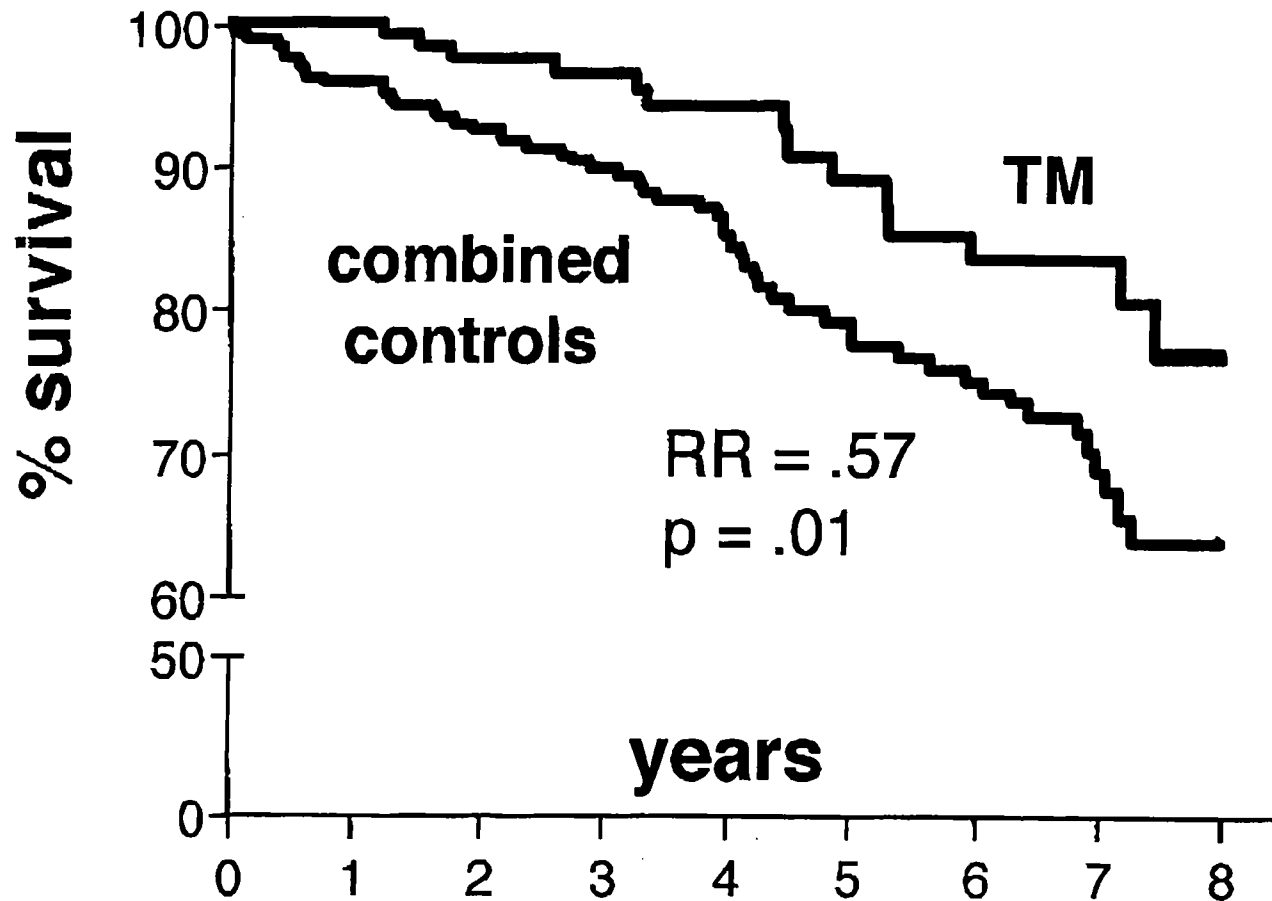
Schneider, RH, Alexander, CN, Rainforth, MR, Salerno, JW, et al. Presented to the Society for Behavioral Medicine Annual Meeting, March 3-6, 1999, San Diego, CA

Cancer Mortality



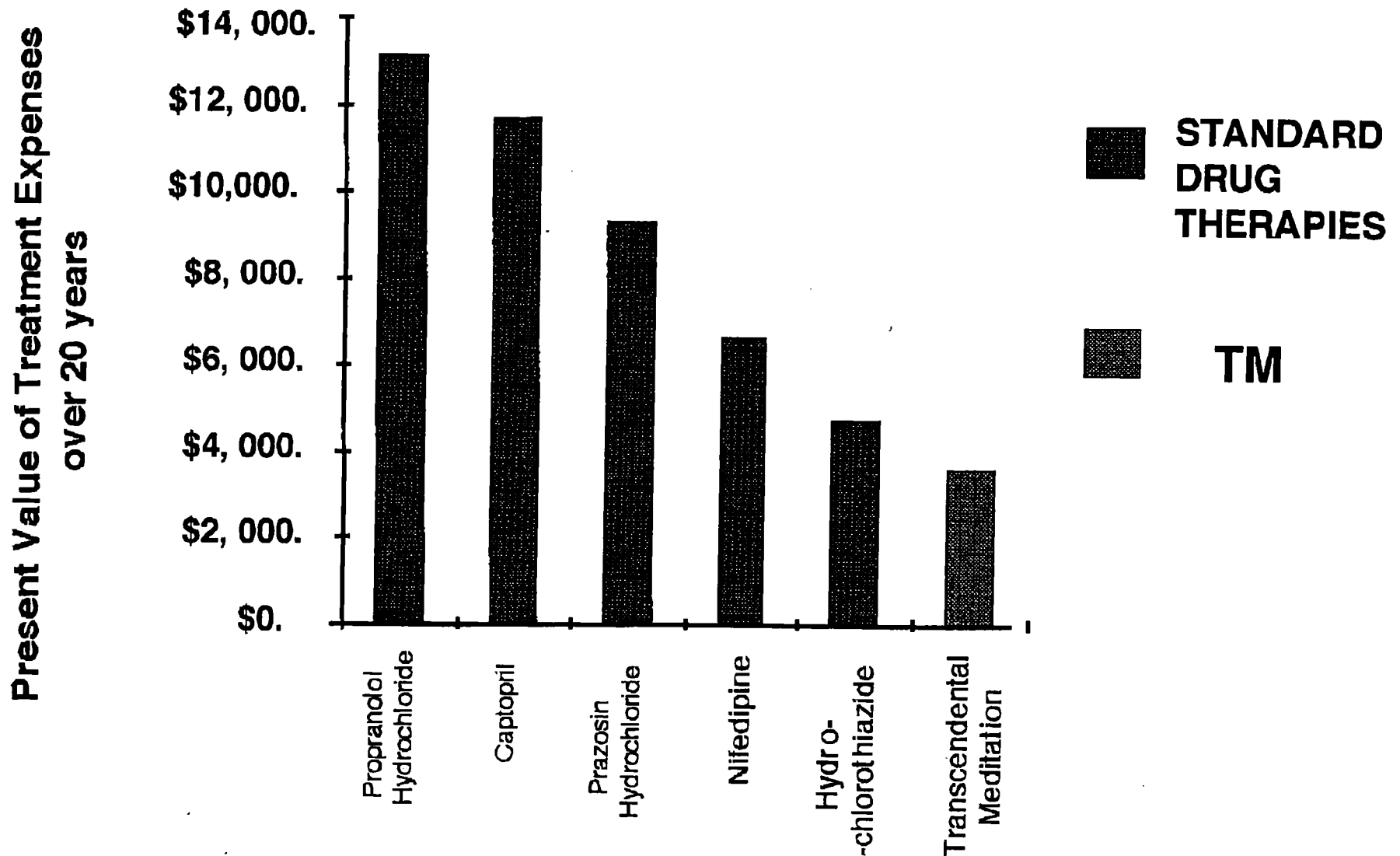
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All-Cause Mortality



Schneider, RH, Alexander, CN, Rainforth, M, Salerno, JW, et al. Presented to the Society for Behavioral Medicine Annual Meeting, March 3-6, 1999, San Diego, CA

Costs of Antihypertensive Treatment



R.E. Herron, R.H. Schneider, et al. Journal of Managed Care. 1996, vol.2, pp. 427-437

Critical Issues and Trends

All Approaches to Preventing or Reversing Effects of Stress Are Not the Same

David W. Orme-Johnson, Kenneth G. Walton



With increasing evidence that sustained stress can have serious pathologic effects,¹ and modern medicine's lack of adequate remedies for these effects, it is no wonder that patients are now trying meditation and relaxation for their stress-related disorders.² Research supporting the value of such approaches also is increasing, as is institutional recognition. A recent NIH Technology Assessment Panel concluded there is "strong evidence for the use of relaxation techniques in reducing chronic pain" and evidence that they reduce insomnia as well.³

According to the latest research, some of these approaches are effective in treating hypertension⁴⁻⁷ while others are not.⁸ Moreover, initial studies suggest that efficacious techniques can reduce symptoms of heart disease⁹ and lower medical utilization and costs,¹⁰⁻¹³ with substantial reductions in mortality and improvements in quality of life in the elderly.^{4,14} However, optimum health improvements and reductions in medical costs through application of appropriate techniques are jeopardized by a widespread misconception.

Reports of physiological effects of meditation in Westerners began appearing over 25 years ago.¹⁵ Shortly afterwards, it was hypothesized that all techniques of meditation and relaxation produce similar reductions in sympathetic arousal, called the "relaxation response," and therefore that all should be equally effective.¹⁶ For many researchers and clinicians alike, this proposal soon became accepted as proven. Now, however, both direct clinical

comparisons and statistical meta-analyses based on hundreds of studies (see Table 1) support an alternative hypothesis, namely, that different techniques produce different outcomes.^{17,18} A qualitative review of 175 studies and 25 reviews concluded that the range of outcomes reflects the different goals and methodologies of these approaches¹⁹ (Table 1). The effects of biofeedback, for example, are usually specific to the system addressed. Electromyographic (EMG) biofeedback reduces muscle tension, whereas blood pressure biofeedback modifies blood pressure, and finger-temperature biofeedback may change peripheral circulation. Moreover, different techniques affecting a particular bodily system may have different effects on that system. Progressive muscle relaxation leads to generalized muscle relaxation, whereas for most people EMG biofeedback reduces tension only in the muscles to which feedback training is applied.¹⁸

Similarly, approaches that influence the autonomic nervous system have different effects at that level. Autogenic training, which involves visualizing pleasant past experiences, may have generalized autonomic effects that differ from the specific autonomic effects of biofeedback on finger temperature, heart rate, skin resistance, or blood pressure.¹⁸

Meditation, relaxation, and other techniques used to reduce or prevent effects of stress differ widely with regard to what the person actually does during these techniques, as well as their respective outcomes. Certain cognitively oriented techniques used in counseling train a person to restructure interpersonal relations to avert stress-provoking interactions. Their effects differ from those of meditation, which appears more effective at reversing endocrine changes due to chronic stress.¹⁹ The cognitive activity required by autogenic training and hypnosis, both of which involve suggestion, is different from the activity required by these cognitively oriented techniques and from that involved in meditation.¹⁸

Moreover, the effectiveness of different meditation and

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Table 1
Comparison of Stress-reduction Techniques

Outcome Measure	Qualitative Review	
	n Studies	Results by Technique [*]
Stress management outcomes¹⁶	175	
Disorders with predominant muscular component (e.g., tension headaches)		BIO-EMG, PMR > A, BIO-A, CT
Disorders with predominant autonomic component (e.g., hypertension, migraine headache)		A, BIO-A > BIO-EMG, CT, PMR
Disorders with predominant cognitive component (e.g., anxiety, phobias)		CT > A, BIO-A, BIO-EMG, PMR
Outcome Measure	Quantitative Meta-analyses	
	n Studies	Results by Technique [†] (Effect Size)
Clinical symptoms^{‡20} (Anxiety, chronic pain, insomnia, headache, acute pain, hypertension)	48	PMR(-0.63), H(-0.54), A(-0.46) > RR (-0.10)
Physiological relaxation^{§21}	32	
Basal GSR		TM(0.83) > UR(0.18)
Spontaneous GSR		TM(-0.78) = UR(-0.40)
Respiration rate		TM(-0.46) > UR(-0.11)
Heart rate		TM(-0.21) = UR(-0.14)
Plasma lactate		TM(-0.82) > UR(-0.23)
Reduced hypertension⁶	26	BIO-A = CT = OM = PL = PMR, RR TM > MF > RR [¶] TM > PMR > DE ^{¶5,6} TM > CT ^{¶7}
Trait anxiety²²	146	TM(-0.89) > OR(-0.41) = OM(-0.37) = PMR(-0.36) ^{**} TM(-0.70) > PL(-0.41) = RR(-0.41) = PMR(-0.38) = BIO-EMG(-0.30) = MM(-0.22) > C(0.003) ^{††}
Self-actualization²³ (Overall mental health)	42	TM(0.78) > OR, PMR(0.27) = OM(0.26)
Affective outcomes²⁴ (e.g., reduced anxiety, increased self-concept)	51	TM(0.62) > Z(0.49) > RR(0.29)
Substance use^{‡‡25}	198	
Cigarettes		TM(-0.87) > UT(-0.39), ^{¶¶} PT(-0.29), ^{¶¶} IC(-0.18), ²⁶ SH(-0.08) ²⁶
Alcohol ^{§§}		TM(-0.55) > PP(-0.33), ²⁷ R(-0.15), DUI(-0.10), ²⁸ PE(-0.07) ²⁷
Illicit drugs		TM(-0.83) > PP(-0.47), ²⁸ PE(-0.13) ²⁷

* "A > B" is the suggested conclusion based on a qualitative review that treatment A is superior to treatment B.

† Effect sizes relative to control conditions. ">" indicates significant difference between treatments of at least $p < 0.05$; "=" indicates no significant difference between treatments; "." (comma) indicates no test of significance was conducted between treatments; (minus sign) preceding an effect size indicates a decrease (e.g., decreased anxiety).

‡ Only techniques with more than one study were included in this table.

§ Changes from baseline to during TM or UR; mean baseline = 14.6 min.

|| Effect sizes not reported and not calculable from the reported data. Mean blood pressure decrease across all treatments was 2.8 mm Hg systolic and 1.3 mm Hg diastolic, which was not statistically significant.

¶ Published study not included in the meta-analysis¹⁵ that met the selection criteria of the meta-analysis (e.g., random assignment, statistically and clinically relevant outcomes, low dropout rate, credible control conditions).

** Data from Table 4, studies matched for population, adjusted for duration, attrition, and follow-up hours that were published in journals or dissertations, random assignment with alternate treatment, and authors neutral or negative towards the TM technique.

†† Data from Figure 1, all studies, subcategories of meditation and relaxation.

‡‡ The table reports mean effect sizes. For studies with better designs (i.e., longitudinal and random assignment), the TM effect sizes were at least as high or better (-0.97 for cigarettes, -0.55 for alcohol, and -0.91 for illicit drugs).

§§ Reduced use by heavy social drinkers or alcoholics.

||| Reduced use of cannabis products, LSD and other hallucinogens, and narcotics.

Abbreviations: A, autogenic combinations; BIO-A, biofeedback-autonomic (blood pressure, finger temperature); BIO-EMG, biofeedback-EMG; C, concentration meditation; CSM, clinical standardized meditation; CT, cognitive techniques (cognitive restructuring, adaptive emotional learning strategies, imagery); DE, diet exercise control (low sodium, etc., for blood pressure reduction); DUI, driving under the influence programs (alcohol abuse education, psychotherapy, probation); H, hypnosis; IC, individual counselling; MF, mindfulness meditation; MM, mantra meditation; OM, other meditation than TM (e.g., C, MF, MM, RR, Z); OR, other relaxation than PMR; PE, preventative education programs; PL, placebo control (e.g., sham biofeedback, pseudo meditation); PMR, progressive muscle relaxation; PP, peer pressure resistance programs; PT, pharmacological treatment (nicotine replacement, clonidine); R, relaxation (BIO-EMG, CSM, CT, PMR, RR); RR, relaxation response techniques; SH, self-help kits; TM, Transcendental Meditation technique; UR, unstylished relaxation; UT, unconventional treatment (acupuncture, sensory deprivation, H, R); Z, Zen.

relaxation techniques varies widely. Ten meta-analyses^{6,20-28} covering a total of 475 studies show a ninefold difference in effect sizes among techniques, ranging from -.003 (no effect) to .89 (a strong effect, see Table 1). For example, meditation techniques that require concentration do not reduce anxiety whereas other meditation and relaxation techniques do, suggesting that intentional, extended focus is not effective in reducing anxiety.²² Furthermore, details of how the techniques are practiced are important. For example, when controlling for expectation, duration of practice, experimenter bias, strength of experimental design, and other factors, meta-analyses have found the Transcendental Meditation® (TM®) technique, with its basis in the ancient Vedic tradition,²⁹ to be more effective than the clinically derived approaches that are modeled after it in reducing anxiety,²² improving psychological health,^{23,24} and reducing tobacco, alcohol, and drug use.²⁵

These and additional studies clearly oppose the hypothesis that all meditation and relaxation techniques have equivalent effects. Consequently, it is erroneous to assume that because the efficacy of one technique is proven, any other will do as well. It is equally erroneous to conclude that because one technique fails to produce a desired result, all will fail. Research must support the effectiveness of a particular approach before that approach can be applied appropriately. For greatest benefit to society, it is crucial that research on stress reduction and prevention techniques uphold the same standards used in other research.

Acknowledgments

*Transcendental Meditation and TM are service marks registered in the US Patent and Trademark Office, licensed to Maharishi Vedic Education Development Corporation and used under sublicense.

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Divider Title: Eddy

Assessment of Intensive Lifestyle Changes for the Treatment of Coronary Heart Disease

David M. Eddy M.D., Ph.D.

July 12, 2000

Anna Silberstein

Summary

This is a brief assessment of the effects of the "Comprehensive Lifestyle Program" of intensive lifestyle changes on the health and economic outcomes of patients who have documented coronary artery disease, and who would otherwise be recommended for revascularization. This program was developed and studied by Dean Ornish, M.D., and his colleagues at the non-profit Preventive Medicine Research Institute and the UCSF School of Medicine. The program has been standardized and consists of a low fat, low cholesterol vegetarian diet; exercise; smoking cessation; stress reduction and psychosocial support.

There is good evidence from one small randomized controlled trial and a larger multi-site, non-randomized but matched controlled study that in this population, the Comprehensive Lifestyle Program will improve cardiac risk factors, reverse coronary artery occlusion, markedly reduce angina, and obviate the need for invasive procedures in the majority of patients. The evidence also indicates that, even under a very conservative set of assumptions, the program will at least be cost neutral to third party payers, and very probably will save money.

Formulation of the assessment

Patients: The assessment applies to men and women who meet the following criteria

- Signs of coronary artery disease sufficiently severe to put them at significant risk of having a myocardial infarction. The severity of the disease could be documented by any of the following:
 - Coronary angiogram
 - >70% LAD
 - >70% RCA
 - >70% left circumflex
 - Reversible perfusion defect on nuclear imaging study
 - Inducible wall motion abnormality on stress echo
 - Cardiac PET scan with thallium-201 showing perfusion defect
- Recommendation from their physician to undergo revascularization (CABG or angioplasty) in the near future
- Willingness to undergo intensive lifestyle changes
- No factors that would exclude them because of especially severe or unstable disease. Such factors would include but not be limited to: acute MI within 2 weeks, left main disease with >50% occlusion, three vessel disease with decreased ejection fraction, and unstable angina.

White House Commission on Complementary and Alternative Medicine
December 5, 2000
Anna L. Silberman
Highmark Blue Cross Blue Shield
Lifestyle Advantage

1. Why and how did you select the Ornish program?

Heart disease is the number one killer of Americans – nationally and among Highmark members. The scientific evidence proved clinical and cost effectiveness. The Ornish Program is less painful, less expensive and more effective for the long term than the alternatives. It's the clinically, financially, and socially responsible thing to do.

2. Describe any data collected on its clinical effectiveness, cost-effectiveness, or patient satisfaction; what did these data show?

See attached outcome chart, Dr. David Eddy's report and several sample case studies.

3. How much does it cost your members to participate in this program?

Currently, the Program is offered free of charge to all members of any Highmark product.

(Highmark documented cost savings are \$17,000 per participant. By offering the Ornish Program free of charge, we have experienced a "win-win" situation: 1) We have provided a unique option that reduces the need for invasive procedures, i.e. bypass surgeries, angioplasties, while members become healthier; 2) the Program has generated significant cost savings.)

4. Based on your experience with the Ornish program and other CAM products and practices, what policy recommendations do you have for the Commission?

1. Continue to support scientific investigations into CAM treatments, to separate what is effective from what is not.
2. Promotion of proven CAM interventions to the public.
3. Influence health plans to reimburse for evidence-based CAM interventions.

Highmark Dean Ornish Program

12 Week Outcomes For The First 10 Cohorts

September 5, 2000

Of the 239 participants who completed the 12 week portion of the program since January 1998, there have been no reported deaths, heart attacks or bypass surgeries. Four participants underwent angioplasties and one participant experienced a stroke.

	Number of Participants	Average Score at Baseline	Average Score at 12 Weeks	Average Change	Percent Change	P Value
Experienced Angina in Past 30 Days	231	67 people	29 people	NA	-57%	P <.001
Total Cholesterol (mg/dl)	214	198.4	175.7	-22.7	-11.4%	P <.0001
HDL Cholesterol (mg/dl)	211	44.4	40.5	-3.9	-8.8 %	P <.0001
LDL Cholesterol (mg/dl)	198	114.4	98.1	-16.3	-14.2%	P <.0001
Triglycerides (mg/dl)	213	205.0	190.1	-14.9	- 7.3%	NS
Exercise Capacity in Minutes (BRUCE)	191	8.9	10.8	+1.9	+21.3%	P <.0001
Oxygen Capacity (METS)	191	10.4	12.5	+2.1	+20.2%	P <.0001
Weight (lbs.)	230	193.8	184.2	-9.6	-4.9%	P <.0001
Body Composition (% body fat)	190	28.5	25.5	-3.0	-10.5%	P <.0001
Systolic Blood Pressure (mmHg)	203	130	122	-7.8	-6.1%	P <.0001
Diastolic Blood Pressure (mmHg)	202	79	73	-6.7	-7.6%	P <.0001
Depression Scale (CES-D)	210	12.2	6.1	-6.15	-50.1%	P <.0001
	210	8.5	6.9	-1.6	-18.8%	P <.0001

Treatment: The treatment to be assessed is the “Comprehensive Lifestyle Program” described above. It consists of the following elements:

- Nutritional counseling designed to achieve a diet that is
 - Vegetarian
 - Low fat (<10% of calories)
 - Low cholesterol (<5mg/day)
 - 15% protein
 - 75% complex carbohydrates
 - augmented with vitamin B-12
- Cessation of smoking
- Stress management
- Moderate aerobic exercise
- Group support meetings

The content and methods of the core program have been standardized, and a training program has been created and demonstrated in a wide variety of settings.

Alternative treatment: The Comprehensive Lifestyle Program will be compared to various combinations of interventions that can include the following, at the discretion of the patient’s physician:

- “Usual” recommendations for changes in lifestyle as recommended by personal physicians. These recommendations can be expected to vary widely from physician to physician
- Cholesterol lowering drugs
- Immediate bypass or angioplasty

Outcomes of interest: The effect of the core program on following outcomes will be assessed:

- Biological outcomes:
 - Weight
 - Blood pressure
 - Lipid levels
 - Percent occlusion of the coronary arteries
- Health outcomes
 - Angina
 - Myocardial infarction
 - Cardiac related deaths
- Procedures
 - Angioplasties
 - CABG
 - Cardiac related hospitalizations
- Costs
 - Costs of procedures, myocardial infarctions, and other cardiac related hospitalizations

Evidence

The literature search was limited to studies of the Comprehensive Lifestyle Program. It did not include other types of diet, exercise, stress reduction, or smoking cessation programs. There are three main studies that provide information about the Comprehensive Lifestyle Program:

The Lifestyle Heart Trial. This was a randomized, controlled, blinded trial (RCT), originally designed to determine if the Comprehensive Lifestyle Program could cause regression of coronary atherosclerosis. A five-year follow-up has been published that reports the long-term compliance to the lifestyle changes, and the long-term effects of the program on risk factors, biological outcomes, and health outcomes.^{1,2,3,4}

Ninety three patients with angiographically confirmed coronary artery disease were randomly assigned to be offered either the Comprehensive Lifestyle Program (53 patients), or “usual care” as determined by their personal physicians (40 patients). Twenty eight patients (53%) in the first group agreed to participate, and form the “experimental group”. Twenty patients (50%) in the second group agreed to participate, and form the “control group”. Reasons for refusal to participate were not wanting to undergo the lifestyle changes, and/or not wanting to have a second angiogram.

To detect possible biases introduced by the invitational design, the authors collected data on age, marital status, height, weight, reported angina, history of MI, number of diseased vessels, and severity of stenosis, for all patients who were invited into the experimental group but declined. Those who declined were similar to those who volunteered with respect to all available data, except that those who volunteered (1) were more likely to have had a history of angina (87% vs. 65%); (2) had a greater number of stenotic lesions (4.5 vs. 3.5); and (3) had slightly more severely stenosed lesions (2.3 vs. 2.0 on a 3-point scale).

A comparison of the experimental and control groups showed that they were similar with respect to all important risk factors, except that (1) the control group had a higher proportion of women; (2) patients in the experimental group were heavier and taller on average (due largely to the higher proportion of men); (3) patients in the experimental group had slightly lower HDL levels, and lower apolipoprotein A-I levels; and (4) patients in the experimental group had more severe angina.

Based on all the available data, if there was any selection bias caused by the invitational design, its probable effect was to create a higher risk of CAD events in the experimental group. To the extent that such a bias existed, its effect would be to cause the observed results to understate the full effects of the Comprehensive Lifestyle Program. Finally, it is pertinent that at baseline both groups were similar with respect to lifestyle (diet, exercise, smoking, and stress reduction techniques), with both practicing risk reduction behavior consistent with a Step II diet of the National Cholesterol Education Project (NCEP).

Multicenter Lifestyle Demonstration Project. This multi-site, non-randomized, controlled trial was designed to determine if the Comprehensive Lifestyle Program could obviate the need for revascularization in selected patients. Three year results have been published.⁵

The experimental group consisted of 194 patients who had angiographically documented coronary artery disease severe enough to warrant revascularization and who met insurance company criteria for reimbursement for a revascularization. Patients were excluded if their disease was considered to be too severe or if they had signs of active infarction or unstable disease (e.g. >50% stenosis in left main coronary artery, CABG within 6 week or angioplasty within 6 months, chronic unresponsive congestive heart failure, etc.). A control group consisted of 139 patients who were matched for age, gender, left ventricular ejection fraction, and cardiac score, but who had had a revascularization in the preceding month.

The severity of CAD on angiography was similar in both groups. There were no significant differences in age, gender, marital status, employment status, or history of hypertension, hyper-cholesterolemia, diabetes, smoking, or family history of heart disease. However, 54% of the experimental group vs. 32% of the control group were taking lipid lowering drugs. Furthermore, the experimental group had a higher proportion of patients with prior MIs (55% vs. 28%), and longer histories of CAD. The available data imply that if there is a selection bias it is toward a higher risk of CAD events in the experimental group. The main difference in the two groups is that the patients in the experimental group had only been recommended for revascularization, whereas the patients in the control group had already had a revascularization.

Highmark Disease Management Program Study. This non-randomized comparative study used insurance data to estimate the effect of the Comprehensive Lifestyle Program on per-member-per-month (PMPM) costs. The results have been analyzed but not been published in a peer reviewed journal⁶.

Forty nine (49) patients with a diagnosis of CAD were compared to 33 patients who also had a diagnosis of CAD and who expressed interest in the Comprehensive Lifestyle Program, but lived in a service area where the program was not available. While they did not formally participate, it is possible that patients in the comparison group chose to make lifestyle changes on their own. During the year prior to the program, the PMPM costs were very similar in the two groups: \$552 in the experimental group vs. \$537 in the control group.

Quality of the evidence

In my judgment, the overall quality of the evidence is good, and sufficient to permit conclusions about the effects of the program on health and economic outcomes. Compared to other technologies involving lifestyle changes, the quality of this evidence is very good. It is also very good compared to the quality of the evidence for the main alternatives to the program:

- “Usual” recommendations for changes in lifestyle made by personal physicians: These can be expected to vary widely from physician to physician, and have never been systematically evaluated.
- CABG: This has been shown in well designed studies to reduce angina, and to decrease mortality in patients who have severe disease of the left main coronary arteries. Several studies have failed to show any effect on mortality of patients who do not have severe disease of the left main coronary artery.
- Angioplasty: There are no randomized controlled trials that compare PTCA to conservative management.

Results

Adherence to the lifestyle changes. Both the RCT and the demonstration showed that patients who undergo the Comprehensive Lifestyle Program can sustain the lifestyle changes for a prolonged period of follow-up.

In the RCT, patients received scores based on the degree to which they followed the minimum recommended changes in each of the components of the program. Perfect compliance with the minimum recommended changes would receive a score of 1.0. Scores greater than 1 were possible if participants exceeded the minimum recommended levels of change. In the experimental group, the average of the scores at baseline was 0.62. After one and five years the average scores were 1.29 and 1.06, respectively. Thus even after 5 years the patients in the experimental group were still following the minimum recommended changes in lifestyle. In the control group of the RCT, the patients had an average score of 0.60 at baseline -- essentially the same as the experimental group and roughly equivalent to a Step II diet of the NCEP. After one and five years, the average compliance scores for the control group were 0.64 and 0.72, respectively. The pertinence of this is that it created a fairly high hurdle for the Comprehensive Lifestyle Program; any improvements in outcomes would have to be gained “on top of” the benefits achieved by a Step II diet.

In the demonstration program, a similar degree of adherence was shown for all components of the lifestyle program: while the results at five years were slightly lower than the results after the first year, they were all substantially improved over the baseline.

Biological outcomes. Patients who underwent the Comprehensive Lifestyle Program in both the RCT and the demonstration project showed marked and sustained improvements in risk factors and disease severity.

For example, without taking any cholesterol lowering drugs, patients in the RCT had LDL cholesterol levels drop from 149 mg/dL at baseline, to 87 mg/dL at one year, rising only to 115 mg/dL at 5 years. Patients in the control group showed little change in LDL cholesterol levels after one year (166 mg/dL at baseline, to 164 mg/dL at 1 year). After five years their levels had decreased to 139 mg/dL, but even this relatively modest reduction was due in large part to the fact that 60% of the patients – presumably those who needed it most -- were put on cholesterol lowering drugs.

In addition, the RCT showed significant increases in the lumens of stenosed coronary arteries in the patients in the experimental group. In that group the average degree of stenosis decreased 1.75 absolute percentage points after 1 year, and 3.1 absolute percentage points after 5 years. In contrast, the average degree of stenosis in the control group increased 2.3 percentage points after 1 year, and 11.8 percentage points after 5 years. Cardiac PET scans showed substantial improvements in myocardial perfusion in the experimental group but worsening of myocardial perfusion in the control group patients.

Health outcomes. The ultimate test of a treatment is its effect on health outcomes. The RCT provides the best evidence for this; it showed that the Comprehensive Lifestyle Program caused statistically and clinically significant improvements in important health outcomes.

After one l year , the experimental group showed a marked improvement in the frequency, duration and severity of angina. The benefits persisted through the five years of follow-up. In comparison, the control group, which started out with less severe angina, got significantly worse over the first year. By the end of the fifth year they had pulled approximately even with the experimental group, but this gain was no doubt affected by the fact that 3 out of 5 of the patients who had the worst angina were given angioplasties between the first and fifth year. The results are shown in Table 1.

Table 1				
Angina characteristic	Group	Baseline	1 year	5 years
Frequency, times/week	Experimental	5.8	0.5	1.6
	Control	1.4	4.0	0.9
Duration, minutes	Experimental	3.1	1.8	0.9
	Control	3.2	7.6	1.0
Severity, 0 to 7 scale	Experimental	1.5	0.7	0.9
	Control	0.6	1.4	0.6

The effects on the other important health outcomes after five years are shown in Table 2. With the exception of cardiac related deaths, the Comprehensive Lifestyle Program had either a statistically significant or a strong trend toward a beneficial effect on every

outcome. When angioplasties and bypasses are combined, the effect on revascularization procedures is statistically significant. The higher probability of cardiac related deaths is statistically meaningless, being easily explained by random effects.

Table 2			
Event	Experimental	Control	p value
MI	7%	20%	.26
PTCA	29%	70%	<.05
CABG	7%	25%	.14
Other cardiac hospitalizations*	39%	105%	<.001
Cardiac related deaths	7%	5%	.81
Any event	89%	225%	<.001

*excludes hospitalizations for MIs, PTCAs, and CABGs.

The results of the Multicenter Lifestyle Demonstration Project bolster those of the RCT. With regard to angina, of the patients in the experimental group who had angina at baseline, approximately two thirds had no angina at the end of the 1st, 2nd and 3rd years. (The specific question asked at the end of each year was whether the patient had had any angina pain in the previous 30 days.) With regard to revascularizations, despite the fact that all of the 194 patients in the experimental group had CAD that was sufficiently severe to warrant (and meet insurance criteria for) a revascularization procedure, over a follow-up period of 3 years 150 (77%) avoided any procedure. When compared to the comparison group, all of whom had just had revascularization procedures, there were no significant differences in heart attacks, strokes, cardiac deaths, or non-cardiac deaths. The implication is that for at least 3 years, the Comprehensive Lifestyle Program obviated the need for bypasses and angioplasties in about three fourths of patients.

Considering all the evidence, there is an extremely high probability (>99%) that the Comprehensive Lifestyle Program is effective and beneficial compared to “usual care” for patients who have documented coronary artery disease and are recommended to receive revascularization procedures.

Economic effects. The effects of this program on costs were determined in the Multicenter Lifestyle Demonstration Project and in the demonstration conducted by the Highmark Disease Management Program. In the Multicenter Lifestyle Demonstration Project, the average cost of PTCA (with cardiac catheterization) was \$31,000, and the average cost of a CABG was \$46,000. The authors calculated that, compared to the costs of procedures received by patients in the comparison group, the fact that revascularizations were done for only a fourth of the patients in the experimental group implied an average savings per patient of \$29,529, even after the \$7000 cost of the Comprehensive Lifestyle Program is taken into account. There is no way to know how many of the patients in the experimental group would have had revascularizations if they had not participated in the Comprehensive Lifestyle Program. But even if half of them could have avoided revascularization “on their own”, the Comprehensive Lifestyle Program still would have returned a net savings.

The Highmark Disease Management Program provides a more comprehensive analysis, because it included all the charges incurred by an insurance company. In the year prior to the introduction of the program, the group that received the program and the comparison group had similar PMPM costs (\$ 552 vs. \$537, respectively). In contrast, in the year after the program was introduced the costs in the experimental group dropped more than 50% (to \$255), compared to almost no change in the comparison group (\$498). There are no results beyond the first year.

It is notable that one patient in the control group experienced extremely high costs in the year after the program began -- \$75,000 in one month. It is appropriate to include this patient in the calculations. (Certainly it would be inappropriate to exclude a high-cost outlier like this if he or she were in the experimental group). Furthermore, this patient illustrates the great benefit that can be gained by preventing just one serious event. However, it is also instructive to redo the calculations without this outlier. In this case, the PMPM in the control group would also have shown a large decrease in the second year -- from \$537 to \$308.

To estimate the financial effects of the Comprehensive Lifestyle Program over a longer period of time, it is necessary to use a model (Appendix). A simple model that strays the least far from the data can be based on the change in rates of events and procedures observed in the RCT (Table 2). For the costs of angioplasties and bypasses, one source is the Multicenter Lifestyle Demonstration Project that included 333 patients in 8 medical centers. In that study the average cost of an angioplasty was \$31,000 and the average cost of a bypass was \$46,000. Using these costs, and using a conservative estimate of \$5000 for an MI or other cardiac hospitalization, the expected costs over five years for a patient in the experimental group would be about \$14,500 (see the Appendix, scenario 1). This should be compared to a cost of about \$39,500 for a patient in the control group, for a difference of about \$25,000. The cost of the program has been calculated to be about \$7200 per patient, leaving a net decrease in costs (i.e. savings) of about \$17,800. From the point of view of a third party payer, if a 20% co-payment is required the cost of the program to the payer would be \$5760 (scenario 2). This suggests that from the payer's point of view, over five years the program can be expected to save almost \$4 for every \$1 spent.

The costs of angioplasties and CABGs reported for private insurance might overestimate the cost to a public program such as Medicare. To allow for this, more conservative assumptions can be used, based on the DRGs for angioplasties and bypasses. For one large HMO in California (Kaiser Permanente Southern California) these costs are about \$12,000 and \$28,000, respectively. Under these more conservative assumptions, the expected 5-year costs in the experimental and control groups are \$7750 and \$21,650, respectively, for a difference (savings) in costs of admissions and procedures of about \$13,900 per patient. Allowance for a 20% copayment by the patient would leave a 5-year net savings of about \$8150 per patient (scenario 3).

The previous calculations did not take into account the fact that the cost of the program is incurred in the first year, whereas the savings from preventing procedures and admissions will be spread out over the succeeding 5 years. If the savings in procedure costs are discounted, assuming that they are spread evenly through the five year period (i.e. occur at 2.5 years), and assuming a 3% real discount rate, the expected net savings are about \$7150 per patient (scenario 4). This general conclusion is insensitive to any reasonable assumption about the timing of events or discount rates.

The strength of the case for savings is made even stronger by some extreme sensitivity analyses. The program is cost neutral to a third party payer even if the costs of all the procedures are reduced from their (already conservative) values by 50% (scenario 5), or if the rates of all the events and procedures with the Comprehensive Lifestyle Program are doubled (scenario 6).

Additional costs that could be included are the cost of cholesterol lowering drugs and the related office visits. (In the Lifestyle Heart Trial, cholesterol lowering drugs were taken by the majority of patients who received "usual care", but none of the patients who were on the Comprehensive Lifestyle Program.) Office visits for angina could also be expected to be higher in the group that received usual care. The depressions that have been reported with CABGs could increase their costs. Inclusion of additional factors like these could make the financial case for the Comprehensive Lifestyle Program stronger.

In summary, the conclusion that the program is at least cost-neutral, and is probably cost saving, is robust under a wide range of assumptions and sensitivity analyses. While it is never possible to know the exact financial effects of a treatment (or its exact clinical effects, for that matter), all the available evidence suggests that the Comprehensive Lifestyle Program is highly likely to be cost saving, and extremely unlikely to be cost increasing.

*Dr Eddy was reimbursed by the Preventive Medicine Research Institute at his usual rate for the time required to prepare this report.

Cost analysis of Comprehensive Lifestyle Program						
Assumptions	Scenarios*					
	1	2	3	4	5	6
Effectiveness (probabilities of outcomes)						
Comprehensive Lifestyle Program						
MI	7.1%	7.1%	7.1%	7.1%	7.1%	14.3%
PTCA	28.6%	28.6%	28.6%	28.6%	28.6%	57.1%
Bypass	7.1%	7.1%	7.1%	7.1%	7.1%	14.3%
Other cardiac hospitalization*	39.3%	39.3%	39.3%	39.3%	39.3%	78.6%
Death	7.1%	7.1%	7.1%	7.1%	7.1%	14.3%
"Usual care" group						
MI	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%
PTCA	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%
Bypass	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Other cardiac hospitalization*	105.0%	105.0%	105.0%	105.0%	105.0%	105.0%
Death	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Costs						
Cost of procedures						
MI	\$5,000	\$5,000	\$5,000	\$5,000	\$2,500	\$5,000
PTCA	\$31,000	\$31,000	\$12,000	\$12,000	\$6,000	\$12,000
Bypass	\$46,000	\$46,000	\$28,000	\$28,000	\$14,000	\$28,000
Other cardiac hospitalization	\$5,000	\$5,000	\$5,000	\$5,000	\$2,500	\$5,000
Comprehensive Lifestyle program	\$7,200	\$7,200	\$7,200	\$7,200	\$7,200	\$7,200
Discounting						
Average delay (years)	0	0	0	2.5	2.5	2.5
Real discount rate	0.0%	0.0%	0.0%	3.0%	3.0%	3.0%
Copayment for Comprehensive Lifestyle program	0.0%	20.0%	20.0%	20.0%	20.0%	20.0%
Results --expected costs						
Expected costs of procedures						
Comprehensive Lifestyle Program	\$14,465	\$14,465	\$7,751	\$7,199	\$3,599	\$14,397
"Usual care" group	\$39,450	\$39,450	\$21,650	\$20,108	\$10,054	\$20,108
Expected savings from procedure costs	\$24,985	\$24,985	\$13,899	\$12,909	\$6,455	\$5,711
Cost of Comprehensive Lifestyle program	\$7,200	\$5,760	\$5,760	\$5,760	\$5,760	\$5,760
Net savings	\$17,785	\$19,225	\$8,139	\$7,149	\$695	-\$49

* Bold font indicates assumptions that have been changed from the previous scenario

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The Dr. Dean Ornish Program for Reversing Heart Disease
From Highmark Blue Cross Blue Shield
Provided by HealthPLACE

Participant Profile

Participant: Ronald "Ron" XXXXXXXX

Initial Contact: This 53 year-old disabled West Mifflin gentleman contacted us after reading an article in the Greensburg paper about the Ornish program. Ron has diagnosed coronary artery disease, hyperlipidemia and a strong family history of heart disease. According to Ron, he has sustained five myocardial infarctions with his first in 1983. He underwent a five vessel CABG in 1983 and three angioplasties during 1988 and 1989. He reportedly sustained a stroke after one of his angioplasty procedures, but suffered no residual effect.

Ron's most recent coronary arteriography in March of this year disclosed total occlusion of the SVG to the RCA, segmental lesions of 60%, 90%, and 99% in the native RCA and a patent SVG to the circumflex artery, which harbored a 50% lesion. There was a 70% occlusion in the obtuse marginal branch, and total occlusion of the left anterior descending with a patent IMA graft. He was deemed ineligible for further surgical treatment. Ron was still having chest pain at rest and using nitroglycerine prior to any activity to prevent the onset of angina.

At the beginning of the program, Ron's medications included: Lisinopril, Simvastatin, Diltiazem, Isosorbide, Metoprolol, Aspirin, Probenecid, Fluvoxamine, Lasix, Folic Acid, Colchicine, Meclizine, Nitroglycerine, and an Albuterol Oral Inhaler.

Phase 1: Prior to the beginning of the program, Ron had begun to make lifestyle changes. He reports that being on disability due to his heart disease, and having to take over 28 pills a day, has made him feel isolated and depressed. Ron and 14 other participants began the intensive, 12-week phase of the year-long program in September 2000. This ten-hour per week program consists of one hour of moderate aerobic exercise, one hour of stress management, one hour of nutrition that includes education and a meal, and one hour of group support. This regimen continues every Monday and Wednesday through December 2000. Ron's main goal is "to stay alive." According to Ron, this program is his last chance since there are no more surgical or medical options available to him.

- Nutrition:** He had begun to modify his diet a month before beginning the program. At that time he weighed 257 pounds. When he began the program he had lost 20 pounds. Ron is 100% compliant with the diet.
- Exercise:** Ron participated regularly in cardiac rehabilitation and exercised at a local gym on a daily basis prior to joining the program. Even with his strict exercise regime, he continued to have chest pain daily. He no longer has chest pain and has not used nitroglycerine for three months. Ron reports over 800 minutes of exercise a week, with no adverse events. Ron wears a heart monitor during exercise and continues to be in a normal sinus rhythm. He has a resting blood pressure of 100/62, a heart rate of 60 and a normal glucose level of 110. Ron is a leader in his group and an outstanding example of how dedication can make all the difference.
- Yoga:** Ron had not had experience with yoga prior to the program, but was looking forward to learning. He describes himself as "Type A" who benefits from the meditation, as well as increasing his flexibility and mental concentration.
- Support Group:** Ron began the program with a sense of loss and feelings of isolation and depression. He now he has sense of belonging and sees positive changes that have renewed his quality of living.
- 6-week Outcomes:** At six weeks Ron has lost over 30 pounds, weighing in at 211 pounds. He has lost a total of 70 pounds since reading *The Dr. Dean Ornish Program for Reversing Heart Disease* book. He has had a total absence of chest pain with an increase in energy and quality of life. Ron's primary care physician is pleased with Ron's improvements and has eliminated two medications from his routine, reducing his medications by eight pills daily.

Current Lipids are as follows:

	Baseline	6-weeks
Total Cholesterol	241	136
Triglycerides	249	81
HDL	40	40
LDL	134	80

The Dean Ornish Program for Reversing Heart Disease
From Highmark Blue Cross Blue Shield
Provided by HealthPLACE

Participant Profile

Participant: Walter XXXXXXXX

Initial Contact: This 45-year-old white male discovered the program through a newspaper article and from his cardiologist in the fall of 1999. In 1996, at 41 years of age, he had his first MI. One year later he had angioplasty with a stent to his right coronary artery. The stent occluded four months later and was redone without relief of his angina symptoms. Three months later he had coronary bypass surgery involving his right internal mammary artery to the right posterior descending artery. His angina symptoms were relieved for a while but returned in April of 1999. His cardiac catheterization on April 19, 1999 demonstrated a 70% occlusion of his left anterior descending artery and a 60% occlusion of his ramus intermedius artery. Medical management was recommended at that time.

Phase 1: Walter and 11 others began the intensive 12-week phase of the year-long program on January 17, 2000. This regimen continued twice a week through April 12, 2000. Walters's goals: get healthy, lose weight and manage his stress.

He was experiencing angina on a regular basis at the beginning of the program. These symptoms subsided within the first two weeks of the program and have not returned. He confessed to me that he had lied about the frequency of his angina on his initial interview because he thought we might not accept him into the program. He now tells me that his angina had been at least daily before starting in the program. He was sure he was headed for a repeat CABG.

Nutrition: Walter's baseline weight was 253 pounds. After 12 weeks he was 229.5 pounds for a total weight loss of 23.5 pounds. As of October 2000 he had lost a total of 60 pounds. Walter lives alone and embraced the opportunity to cook healthy meals. As a catering supervisor, Walter would have his co-workers taste test the food so that he would not stray from the dietary guidelines.

Exercise: His exercise capacity improved by 4 METS during phase I of the program from 10.3 to 14.3 METS. On a recent case management follow up call he stated that he can now run two miles continuously without angina, compared with a slow walk in the beginning of the program that produced angina. He walks and jogs for the majority of his aerobic exercise. His exercise minutes have stayed well above the 180 minutes minimum requirement.

Stress Management: Walter's job is very stressful and he has found the stress management component to be a huge help. As part of his daily routine he reports closing his office door and taking the phone off the hook to practice stress management. He reported that the stress management helped him with his overeating.

Group Support: Walter was very active in the group process. He stated that the program helped him get in touch with himself and he became aware of issues that he had never dealt with. He continues to be active in the ongoing yoga and group support and has been elected Vice President of the Self -Directed Ornish Community.

Phase 2: Walter continues to be an active participant in yoga and group support on a weekly basis. He also participated as a mentor for a new cohort. Walter continues to report an absence of angina and a slower but steady weight loss. He has stayed compliant with all four aspects of the program.

12 week Outcomes: Total cholesterol decreased from 193mg/dl to 114mg/dl.
LDL cholesterol decreased from 84 mg/dl -58 mg/dl.
Triglycerides went from 316 mg/dl to 103 mg/dl.
Total weight loss 23.5 pounds
Angina free for 30 days
Functional Capacity increased by 4 METS

Summary: Participation in the Dr. Dean Ornish Program has made a significant difference in his quality of life and he is a happier person. He probably avoided coronary bypass surgery due to his participation. On a recent case management phone conversation he reported " I feel like I am 20 years old again."

Improvements in Chronic Diseases With a Comprehensive Natural Medicine Approach: A Review and Case Series

Tony Nader, MD, PhD; Stuart Rothenberg, MD; Richard Averbach, MD;
Barry Charles, MD; Jeremy Z. Fields, PhD; Robert H. Schneider, MD

Approximately 40% of the US population report using complementary and alternative medicine, including Maharishi Vedic Medicine (MVM), a traditional, comprehensive system of natural medicine, for relief from chronic and other disorders. Although many reports suggest health benefits from individual MVM techniques, reports on integrated holistic approaches are rare. This case series, designed to investigate the effectiveness of an integrated, multi-modality MVM program in an ideal clinical setting, describes the outcomes in four patients: one with sarcoidosis; one with Parkinson's disease; a third with renal hypertension; and a fourth with diabetes/essential hypertension/anxiety disorder. Standard symptom reports and objective markers of disease were evaluated before, during, and after the treatment period. Results suggested substantial improvements as indicated by reductions in major signs, symptoms, and use of conventional medications in the four patients during the 3-week in-residence treatment phase and continuing through the home follow-up program.

Index Terms: complementary and alternative medicine, chronic disease, Maharishi Vedic Medicine, natural medicine

Chronic diseases are a major public health problem in the United States. Currently, the prevalence of chronic diseases is about 40% in the US population with approximately 100 million Americans suffering from at least one chronic disorder.¹

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This high prevalence raises concerns about the efficacy and limitations of conventional healthcare approaches in preventing and treating these disorders.^{1,2} Such concerns may contribute to the increasing public and professional interest in alternatives to conventional modern medicine. Indeed, Eisenberg² reported that the use of unconventional or alternative therapies is widespread in the United States. For example, in 1990, approximately one third of the US population consulted alternative providers. These 425 million visits per year were more numerous than visits to primary care physicians.² Data from a 1997 report indicate even higher rates of complementary and alternative medicine utilization in the United States.³ However, despite increasing public demand for complementary and alternative therapies, it has been noted that scientific data on safety and efficacy are often lacking.^{2,4-6}

This article reports a pilot study to investigate the potential clinical effectiveness of a comprehensive system of natural medicine, Maharishi Vedic Medicine (MVM), and examines the application of this approach when practiced as an intact multimodality system, as classically described.⁷⁻⁹ Vedic medicine is reported to be the oldest continuously practiced medical system, having its heritage in the ancient Vedic civilization of India.^{8,10-12} Vedic medicine, including Ayur-Veda, has been recognized by the World Health Organization as a sophisticated system of natural medicine with a detailed scientific literature comprising classical medical texts, an uninterrupted oral tradition of classical knowledge predating the written texts, a comprehensive *materia medica*, and a wide breadth of clinical procedures relevant to prevention and treatment of acute and chronic diseases.^{10,12} MVM is a modern revival of ancient Vedic medicine, taking into account an extensive range of diagnostic and therapeutic approaches in accordance with classical texts.¹³ These approaches are said to encompass mental, physical, behavioral, and environmental health.^{7,9,14,15}

Over the past 30 years, several hundred studies have been published on the efficacy, safety, and mechanisms of individual treatment components of MVM, such as the Transcendental Meditation program and certain herbal preparations.^{16,17} These studies suggest that specific approaches of MVM are associated with a lower risk of morbidity and mortality from chronic disorders.¹⁶⁻¹⁸ However, recent consensus guidelines for research on complementary and alternative systems have recommended that traditional systems of medicine be studied in their intact form as clinically used (rather than as isolated components) for clinical efficacy and overall safety.^{4,6,19} Indeed, synergistic effects among individual components are considered essential to the MVM approach to treatment and prevention of chronic diseases.⁹

Furthermore, it has been recently argued that the case study is a valuable method for preliminary studies of complementary and alternative medicine.²⁰ Therefore, this first case series was designed to begin to evaluate the clinical effectiveness of traditional multimodality MVM for the treatment of chronic disease. This report describes clinical outcomes in four patients treated with these protocols. The patients' conditions were (a) sarcoidosis, (b) diabetes/essential hypertension/anxiety disorder, (c) renal hypertension, and (d) Parkinson's disease.

METHOD

The four cases in this study were the first four patients presenting at the Centers for Chronic Disorders (CCD) who met the inclusion criteria of (a) presence of an adult-onset

chronic disease, and (b) a reasonably high probability that we could follow them long-term. The intervention was provided by professionally trained staff at each clinic who were supervised by a physician trained and experienced in the practice of both modern family medicine and MVM for approximately 15 years before the present study.

Standard clinical signs, symptoms, and laboratory examinations for each disease were evaluated before, during, and after the treatment intervention. Clinic blood pressure (BP) measurements during the inpatient phase of our study were routinely taken in the morning at approximately 10 o'clock. Casual BP measurements during follow-up were taken at the patient's convenience. Times for prestudy BP measurements were not available in the patients' medical records (they were taken previously by patients' usual care physicians at various community medical facilities). A standardized quality-of-life assessment battery—the SF-36 general health, physical functioning, role-physical, and mental health subscales—was also administered to each patient before and after treatment.²¹

The multimodality MVM program studied in this series, was applied in the context of a 3-week program of in-residence care followed by a 3-month, home-based program. The key components of the program for all the patients included the following:

Transcendental Meditation and TM-Sidhi program. The Transcendental Meditation (TM) program has been widely practiced and extensively researched in previous literature.^{15,18} Meta-analyses^{22,23} indicate that effects of TM on several chronic disease risk factors appear to be larger than those produced by clinically devised or traditional relaxation programs. These include reductions in sympathetic arousal,^{24,25} smoking and excessive drinking,²⁶ psychosocial stress,²⁴⁻²⁸ and psychosocial cushioning factors.²⁸ Controlled trials show that TM reduces other physiologic risk factors and neuroendocrine contributors to chronic diseases.^{17,18,29,30}

The Transcendental Meditation technique was introduced in the West by Maharishi Mahesh Yogi about 40 years ago and is a primary approach of MVM for stress reduction and self-development.^{7,31} The TM technique is a simple procedure, practiced twice a day for 20 minutes while sitting comfortably with the eyes closed. The practice does not require any changes in personal beliefs, philosophy, or lifestyle. During the technique, the ordinary thinking process settles down and a distinctive psychophysiological state of "restful alertness" is gained. This is indicated by decreased respiration, skin conductance level, plasma lactate and cortisol, and increased frontal alpha and theta EEG power and coherence, increased cerebral blood flow, faster

H-reflex recovery, and shorter latency of auditory-evoked potentials.^{27,32-35}

Pulse diagnosis. The MVM diagnostic approach to the patient includes a classical system of pulse diagnosis whereby the physician palpates the radial pulse to detect patterns that are classically described as corresponding with specific modes of physiological functioning and/or pathophysiological processes.^{8,36} Based on this assessment, as well as on history and clinical examination, the physician prescribed standardized protocols for diet, herbal preparations, physiological purification procedures, exercise, and daily and seasonal behavioral routines (see below).⁸ Participants were also taught a method of self-pulse reading to be used at home.

Vedic sound. Participants received Vedic sound therapy on a daily basis. This included listening to traditional recitations of selected portions of the classical Veda and Vedic literature, which have been suggested to correspond to specific areas of the human physiology and to promote homeostatic self-repair processes in those respective areas.^{7,8,14} The effects of Vedic sound programs may be consistent with modern conceptualizations of the effects of different types of music and sound on the autonomic nervous system and other psychoneurophysiologic processes.^{37,38} Although Vedic sound therapy has been classically recommended, this is, to our knowledge, the first report on the use of Vedic sound therapy in a multimodality traditional Vedic medicine program for the treatment of chronic diseases.

Diet. A traditional Vedic medicine diet was provided in residence and recommended for outpatient follow-up. This diet emphasized fresh vegetables, fruits, grains, nuts, high-fiber content, and dietary sources of antioxidants, vitamins, and minerals; it is similar to other therapeutic diets previously associated with reduced morbidity and mortality from chronic diseases.³⁹⁻⁴¹ Within this broad context, each patient's diet was tailored to compensate for his or her specific physiological imbalances and pathophysiological processes.

Herbal preparations. Herbal preparations from the traditional Ayur-Vedic materia medica were utilized according to clinical indications.⁴² These preparations have been used extensively in traditional and modern clinical settings.^{8,43} Because of putative synergistic effects,⁴⁴ multiple herbs are often combined in a single preparation. Thus, each herbal preparation used in the present trial contained up to 20

individual herbs and fruit extracts. One example is Maharishi Amrit Kalash, which has been evaluated for its antioxidant properties.^{8,16,45}

Physiological purification procedures. The in-residence phase of the program included a series of classical Vedic medicine physical therapies used for physiological purification.^{8,46-48} These therapies are described as eliminating waste products and toxins (eg, oxidized lipids) that accumulate over time from improper diet, poor digestion, stress, and other factors that may obstruct the flow of the body's "inner intelligence."^{8,49}

These treatments were provided in daily sessions of approximately 3 hours' duration and included previously standardized therapies that were prescribed according to the clinical indications of each patient, including specific herbalized oil massages, external heat applications, herbalized steam baths, warm oil applications, and gastrointestinal elimination therapies.^{8,49}

Vedic exercise. Participants were instructed to practice a set of classical Vedic exercises for approximately 10 to 15 minutes twice a day. These exercises have been used in traditional Vedic medical practice for treatment of disease and promotion of health, especially for mind-body integration¹⁴ and are derived from the Yoga aspect of MVM. These included yoga stretching and slow breathing exercises. Previous research studies on these Vedic exercises have found significant reductions in cardiovascular risk factors and in stress-related neuroendocrine markers, and enhanced psychological health.⁵⁰⁻⁵²

Environmental health—effects of the near environment. Analysis of the influence on health of the patient's home and work environments is based on the classical texts of Vedic architecture called Maharishi Sthapatya-Veda.^{7,8,13} This field includes knowledge and practices for the beneficial orientation and layout of homes and office buildings. This approach is consistent with the principles of the recently described syndrome of building-related illness or "sick-building syndrome,"⁵³ although MVM's principles and practice extend beyond considerations of materials' toxicity, ventilation, and so forth. Each participant in the program received an analysis of his or her home and work environments, and recommendations were made based on this analysis.

Environmental health—effects of the distant environment. The Vedic approach to the patient considers that the individual is in a dynamic state of equilibrium with the

entire environment, extending to the universe as a whole, including the influences of the cycles and rhythms of the sun, moon, stars, and planets. This may correspond in part to modern understandings of chronobiology.⁵⁴ The current program included assessment of risk factors, future health trends and recommendations for prevention derived from this traditional approach.⁷

Collective health. Previous research has shown that practice of the Transcendental Meditation program and its advanced program (the TM-Sidhi program) in groups has beneficial effects on health.^{15,55} Group meditation was recommended for participants in this study.

RESULTS

Case 1: Sarcoidosis

A 56-year-old White female patient presented to the CCD in Dallas with classic signs and symptoms of multi-system Stage II sarcoidosis (see Table 1). Nine months previously, the patient had noted the appearance of bilateral olecranon masses. Two months later, she began to experience severe fatigue, dyspnea on exertion, malaise, arthralgias, myalgias, episodic iritis, and other symptoms that substantially reduced her quality of life. The patient was evaluated in early June 1997 at an academic medical center in New Orleans, where chest radiography and a CT scan revealed mediastinal and hilar lymphadenopathy, multiple pulmonary nodules, interstitial pulmonary findings, and a mass in the region of the porta hepatis. Tomograms of the kidneys, ureter, and bladder revealed renal calculi. Blood chemistries revealed elevated levels of angiotensin converting enzyme (ACE) (195, normal 17–70 units/L); erythrocyte sedimentation rate (ESR) (27, normal 0–20 mm/min), and C reactive protein (CRP) 1.2 (normal 0.2–0.8 mg/dL). The diagnosis of sarcoidosis was made when biopsy of pretibial skin lesions revealed noncaseating granulomatous dermatitis. The patient refused oral corticosteroid therapy but did consent to intermittent ophthalmic steroid drops.

A physical exam revealed an obese woman (220 lbs) complaining of worsening symptoms. The lungs were clear. Multiple small nodules were noted over both eyelids and olecranon masses were noted bilaterally. Small non-nodular erythematous skin lesions were noted over the left proximal anterior tibia and dorsum of the right foot. Screening biochemistries were normal except for the ESR, which was elevated at 85 mm/min (normal 0–30 mm/min).

After admission to the center, the patient underwent a 26-day course of traditional Vedic medicine therapy as described above.

During treatment, the patient reported diminished joint and muscle pains and improvement in her breathing. By discharge (Day 27), the olecranon masses and eyelid nodules had decreased and she reported improvements in breathing, energy, and physical exertion, and decreases in fatigue and other symptoms. The ESR and CRP levels had fallen. The ACE value was essentially unchanged. A chest radiograph showed diminution in bilateral hilar adenopathy. The patient also improved significantly on the standardized self-assessment battery SF-36.

The patient was placed on a home-care program including dietary recommendations and herbal food supplements, and continued to improve. One month postdischarge, a CT chest scan at the center in New Orleans showed a decrease in size of hilar and paratracheal lymph nodes and improvement in interstitial disease. Pulmonary function tests revealed mild small airways obstruction with normal diffusion capacity and oximetry. Skin lesions were noted to be resolving, olecranon masses and eyelid nodules were substantially reduced in size, and no clinical evidence of iritis was found. Previously abnormal ESR and CRP values were all reduced and ACE values had decreased substantially. Eight months after treatment, the patient remained free of dyspnea, iritis, fatigue, and other symptoms. Physical examination revealed resolution of olecranon masses and eyelid nodules.

Eighteen months after discharge, the patient remained free of dyspnea, iritis, fatigue, fevers, and other symptoms. She had normal energy and reported being able to engage in vigorous activity (eg, shoveling earth in her garden) without shortness of breath or fatigue. Physical examination revealed complete resolution of olecranon masses, skin rashes, and eyelid nodules.

Case 2: Diabetes Mellitus, Essential Hypertension, Anxiety Disorder

A 55-year-old White male presented for admission to the Dallas CCD with diagnoses of non-insulin-dependent diabetes mellitus (of 12 years' duration), hypertension (20 years), and anxiety disorder (20 years) (Table 2). His diabetes had been managed on diet therapy alone until 3 years prior to admission, at which time he started glyburide and metformin. Home fingerstick fasting blood sugars (mean 212 mg/dL for 30 days prior) and hemoglobin A_{1c} values (8.4 units 1 week prior) were elevated preceding admission. His body weight was low-normal at 147 pounds (height 69 in). There was no history of diabetic complications. The patient had a history of Stage I hypertension treated with an ACE inhibitor (enalapril) for 2.5 years. A 2-week trial off medication 5 months before admission had resulted in

TABLE 1
Patient Measurements Before and After Application of a Comprehensive Natural Medicine Regimen to Treat Sarcoidosis

Outcome measure	Pre-treatment I ^a	Pre-treatment II ^b	Post-treatment I ^c	Post-treatment II ^d	Post-treatment III ^e	Normal range
CT scan						
Right paratracheal node	1.6 × 2.2	—	—	1.4 × 1.9	—	—
Subcarinal node	2.1 × 4.8	—	—	1.3 × 3.2	—	—
Dominant lung nodule (RLL)	1.9 × 2.7	—	—	1.9 × 2.7	—	—
Porta hepatis mass	4.4 × 5.4	—	—	4.2 × 5.4	—	—
Olecranon masses (cm)						
Left	—	8 × 7	5.5 × 4.5	—	0 × 0	—
Right	—	4 × 4	3.5 × 3.5	—	0 × 0	—
Eyelid nodules	Present	Present	Diminished	Absent	Absent	—
Functional respiratory status		Dyspnea and wheezing after flight of stairs	No dyspnea or wheezing after 2 flights of stairs	—	No dyspnea or wheezing after 2 flights of stairs	—
ACE levels (units/L) ^f	195	—	—	119	—	17–70
	—	—	186	—	—	8–52
	—	—	—	—	25.9	6.1–21.1
SF-36 subscales ^g						
General health	—	45	67	—	—	71.95 ± 20.3
Physical functioning	—	40	80	—	—	84.15 ± 23.3
Role-physical	—	0	100	—	—	80.96 ± 34
Mental health	—	52	84	—	—	74.74 ± 18.1

^aMeasurements performed at an academic medical center (New Orleans) before admission to the Center for Chronic Disorders (CCD).

^bMeasurements performed on admission to CCD (Dallas).

^cMeasurements performed on discharge from CCD (Dallas).

^dMeasurements performed at an academic medical center (New Orleans) 1 month after discharge from CCD.

^eMeasurements performed at a medical center (Fairfield, Iowa) 8 months after discharge from CCD.

^fVariations in normal range reflect ranges for different laboratories where assays were done.

^gNormal range are means ± SD.

return of elevated blood pressure levels (160/90 mm Hg). For the preceding 20 years, the patient had panic disorder with depressive features, which was treated with sertraline for the 2 years preceding admission.

Following admission, the patient began a 21-day in-residence program of treatment, which included the MVM components described above. His blood pressure was in the range of 100–115/60–75 during the first 3 days and enalapril was tapered and then discontinued on Day 6. The blood pressure levels remained in the low-normal range without medication throughout the remainder of the treatment program (Days 12–21). Daily fasting blood sugars also decreased substantially (see Table 2). Two-hour postprandial blood sugars were 143 on Day 13 and 137 on Day 20. The decreases in blood sugar occurred even though metformin was tapered fourfold by Day 12. The patient's mood

improved considerably during the course of treatment, and anxiety and depression were absent. Sertraline was discontinued on Day 13. Evaluation of SF-36 indicated improvements in the general health subscale, the mental health subscale, the composite physical outcome score, and the composite mental outcomes score.

At discharge, the patient was asymptomatic and was placed on a home regimen of dietary therapy, herbal supplements, the Transcendental Meditation and TM-Sidhi program, Vedic daily health routine, and exercise. He was also instructed to continue glyburide 2.5 mg and metformin 500 to 1000 mg daily. A follow-up hemoglobin A_{1c} test at 3 months showed a significant decrease (7.4 units) that appeared to reflect the reduction of blood sugar levels during the preceding 90 days. The blood pressure readings and mood remained normal off medication 3 months postdischarge.

TABLE 2
Patient Measurements Before and After Application of a Comprehensive Natural Medicine Regimen to Treat Hypertension, Diabetes, and Anxiety

Outcome measure	Pretreatment I ^a	Posttreatment I ^b	Posttreatment II ^c
Systolic BP (mm Hg) (nl < 140)	122 ^d	115 ^e	122 ^f
Diastolic BP (mm Hg) (nl < 90)	86 ^d	71 ^e	79 ^f
Anti-hypertensive medication	Enalapril, 5 mg. q.d.	None	None
Fasting blood sugar (mg/dL)	212 ^g	119 ^h	134 ⁱ
Hemoglobin A _{1c}	8.4		7.4
Hypoglycemic medications (daily dose)	Metformin 2000 mg; Glyburide 2.5 mg	Metformin 500 mg; Glyburide 2.5 mg	Metformin 1000 mg; Glyburide 2.5 mg
Psychotropic medication	Sertraline, 25 mg. q.d.	None	None
SF-36 subscales ^j			
General health	35	60	71.95 ± 20.3
Physical functioning	80	95	84.15 ± 23.3
Role-physical	75	100	80.96 ± 34
Mental health	52	76	74.74 ± 18.1

^aOn admission to the Center for Chronic Disorders (CCD).

^bAt discharge from CCD.

^cThree months postdischarge from CCD.

^dAverage of 8 readings over 6 months before admission (on Enalapril, see column two).

^eAverage daily readings over last 10 days of treatment (off anti-hypertensive medication).

^fAverage of 8 readings over 3 months after discharge (off anti-hypertensive medication).

^gAverage of daily readings for 30 days before admission.

^hAverage of daily readings for last 10 days of treatment.

ⁱAverage of daily values during third month postdischarge.

^jNormal range are means ± SD.

Case 3: Renal Hypertension

A 47-year-old woman presented to the CCD in Chicago with a 30-year history of hypertension from renal parenchymal disease secondary to obstructive uropathy. At age 17, the right ureter was surgically repaired. According to medical records, her blood pressures were in the Stage I–II hypertension range for most of her adult life. During the 2 months before admission, she averaged 146/97 mm Hg home BP.

On admission, the patient's physical examination and routine blood and urine biochemistries were normal, except that creatinine clearance was reduced to 67 mL/min, and office BP was 150/105 mm Hg. During the 3 weeks of the in-residence program, BP remained essentially unchanged. However, creatinine clearance at discharge was 85 mL/min (within the normal range).

Follow-up during the 2 months immediately after dis-

charge revealed that home BP had decreased to an average of 129/85 mm Hg without medication. Improvements in quality of life were reported on the SF-36 (see Table 3).

One year later, the patient continued to be normotensive without medication, with home BP during the 12th postdischarge month averaging 130/84 (average of 8 readings).

Case 4: Parkinson's Disease

A 49-year-old woman diagnosed with Parkinson's disease (PD) at the age of 41, and treated regularly by a neurologist since that time, presented for admission to the Dallas CCD (see Table 4). On carbidopa-levodopa for the preceding 5 years (CR preparation), symptoms had recently worsened. Despite her use of the long-acting drug preparation, she reported that the carbidopa-levodopa effect wore off after 3 to 4 hours. Selegiline and bromocriptine were tried, but the patient was unable to tolerate these because of adverse drug reactions. In the month before admission, the

TABLE 3
Patient Measurements Before and After Application of a Comprehensive Natural Medicine
Regimen to Treat Renal Hypertension

Outcome measure	Pre-treatment	Post-treatment I	Post-treatment II	Normal range
Systolic BP (mm Hg)	146 ^a	129 ^b	130 ^c	< 140
Diastolic BP (mm Hg)	97 ^a	85 ^b	84 ^c	< 90
24 h creatinine clearance (mL/min)	67 ^c	85 ^d	—	80–120
SF-36 subscales ^f				
General health	72	95	—	71.95 ± 20.3
Physical functioning	80	95	—	84.15 ± 32.3
Role-physical	25	100	—	80.96 ± 34
Mental health	88	92	—	74.74 ± 18.1

^aAverage of 20 readings taken over 2 months before admission to the Center for Chronic Disorders (CCD).

^bAverage of 26 readings taken over 2 months after CCD discharge.

^cTaken on admission.

^dTaken 3 weeks after discharge.

^eAverage of 8 readings taken during 12th month after CCD treatment.

^fNormal range are means ± SD.

patient reported increasingly frequent episodes of freezing-up, immobility, and other symptoms. Following admission, the patient began a 21-day in-residence program, which included the MVM components described above.

During treatment, the CCD medical staff observed that the patient showed significant generalized improvement (eg, markedly reduced dyskinesia, improvements in gait, speech, handwriting, and postural stability). These improvements continued until discharge. The patient also showed improvement in the SF-36 health battery.

The patient was evaluated twice by a neurologist after completing the program. On the Short Parkinson's Evaluation Scale, the patient showed noticeable improvement in gait, postural stability, and dyskinesia. The patient had experienced some increase in tremor during this period and was taking carbidopa-levodopa 700 mg daily.

The patient returned to the CCD for two subsequent 21-day courses of therapy, at 4 months and 11 months, respectively, after discharge from the first treatment. During these subsequent treatments, freezing episodes ceased and further improvements in tremor, fingertapping, handwriting, gait, and postural stability were noted. Carbidopa-levodopa was reduced to 600 mg. Subsequent evaluation by her usual-care neurologist following discharge from each of these programs (2 weeks and 6 weeks, respectively) demonstrated further improvement on the Short Parkinson's Evaluation Scale. The Short Parkinson's Evaluation motor subscale score

decreased markedly to 4 after the second course of treatment and to 3 after the third course. The complications of therapy subscale decreased to 1 and then to zero. Both the mental subscale and activities of daily living subscale decreased to zero and remained at this level after the third treatment course. Further improvement in the SF-36 battery was also noted after each of these treatment programs. Three months after discharge from the third treatment course, she continued on carbidopa-levodopa 600 mg per day and reported she was maintaining these improvements in function and quality of life.

COMMENT

The present series of patients with sarcoidosis; diabetes essential hypertension, anxiety disorder; renal hypertension; and Parkinson's disease demonstrated a range of clinically significant improvements after participating in an intensive multimodality program of traditional natural medicine—MVM. These findings extend previous controlled studies on individual modalities of MVM, which have shown reductions in chronic disease risk factors as well as morbidity and mortality from a range of chronic diseases.^{15–18,56–58}

The present study used an integrated set of diagnostic and therapeutic modalities, as is traditionally used in the classical Vedic medicine approach to the treatment of chronic disorders. The approach of studying traditional systems as

TABLE 4
Patient Measurements Before and After Application of a Comprehensive Natural Medicine Regimen to Treat Parkinson's Disease

Outcome measures ^f	Pre-first treatment ^a	Post-first treatment ^b	Pre-second treatment ^c	Post-second treatment ^d	Post-third treatment ^e
I. Motor evaluation total score	14	11	12	4	3
II. Complications of therapy total score	9	1	5	1	0
III. Mental total score	1	0	0	0	0
IV. Activities of daily living total score	10	4	5	0	0
V. Hoehn & Yahr staging ^g	3	2	2	2	2
VI. Scoring of motor fluctuations ^h	C	A	B	A	A
SF-36 subscales ^f					
General health	55	87	—	72	77
Physical functioning	45	55	—	65	80
Role-physical (RP)	25	75	—	75	100
Vitality	40	45	—	30	55
Physical summary	34.48	43.48	—	43.82	52.18

^aOn first admission to the Center for Chronic Disorders (CCD).

^b6 weeks after first CCD program.

^cOn second admission to CCD.

^d2 weeks after second CCD program.

^e6 weeks after third CCD program.

^fI–VI are from Rabey et al. Evaluation of the Short Parkinson's Evaluation Scale: A new friendly scale for the evaluation of Parkinson's disease in clinical drug trials. *Clinical Neuropharmacology*, 1997;20:322–337. Except for V and VI, scores for individual items ranged from 0 (*no disease*) to 3 (*severest disease*).

^g0 = no signs of disease; 1 = unilateral disease; 2 = bilateral disease; 3 = some postural instability, mild–moderate bilateral disease, physically independent; 4 = severe disability but still able to walk or stand unassisted; 5 = wheelchair bound or bedridden unless aided.

^hA = no motor fluctuations or dyskinesias; B = dyskinesias and/or akinetic episodes and/or freezing gait that affect daily life; C = dyskinesias and/or akinetic episodes and/or freezing episodes that affect daily activities; D = dyskinesias and/or akinetic episodes and/or freezing gait that significantly affect activities of daily life; require considerable assistance for activities of daily life.

intact multimodality systems has been recommended in recent consensus guidelines for research on complementary and alternative medicine.^{4,6,19} However, to our knowledge, this is the first report in current medical literature of the application of Vedic medicine in its complete, traditional form for the treatment of chronic diseases.

The prognosis of sarcoidosis typically depends on the stage of the disease and on other clinical factors.⁵⁹ The present patient was Stage II (pulmonary interstitial disease and hilar adenopathy) with four of seven clinical markers of poor prognosis.⁵⁹ At the time of admission, her symptoms were worsening. Conventional treatment with cortico-steroids may reduce symptoms but is associated with substantial adverse effects and risk for iatrogenic disease.⁶¹

Although the physiological mechanisms for the presumed regression of the sarcoidosis were not evaluated in this study, modulation of immune functioning may have contributed to the overall therapeutic effect. Immunomodulatory effects have been reported elsewhere for various MVM modalities.^{61–63}

Several of the MVM modalities used have previously been reported to have antihypertensive effects and may have contributed to the observed reductions in BP in both the primary and secondary hypertension cases in this series. For example, previous research has reported that the Transcendental Meditation technique and the advanced TM-Sidhi program are effective in the treatment of essential hypertension.^{23,64,65} Also, several Vedic herbal preparations, as well

as certain yoga exercises, have been found to reduce cardiovascular risk factors, including BP.^{41,66,67} These effects may be mediated in part through the sympathetic nervous system and related neuroendocrine factors. In addition, the improved creatinine clearance in the patient with renal parenchymal hypertension suggests improvement in renal function, perhaps through enhanced renal blood flow.⁶⁸ The present approaches are consistent with the recommendations of the Joint National Committee for nonpharmacological treatment of hypertension as initial or adjunctive therapy for patients with hypertension.⁶⁹ This alternative program may obviate or mitigate the need for pharmacologic therapy that is frequently associated with adverse effects, relatively high cost, and low compliance over the long-term.^{23,57,69-71}

Previous data on herbal preparations and stress reduction approaches included in the MVM chronic disorders program suggest that these may have contributed to the improved glucose tolerance in diabetes mellitus^{71, 72} documented in the present study. In addition, the therapeutic diet in this program included features consistent with current recommendations for nutritional treatment of diabetes—emphasizing generous amounts of complex, unrefined carbohydrates and fiber, while restricting total fat to less than 20% to 25% of total energy consumed.⁷³ Protein sources included low-fat milk, legumes, and lean cuts of poultry. Lunchtime was recommended as the largest caloric intake, and complex carbohydrate snacks were provided to meet energy needs when appropriate.

Regarding anxiety, one randomized, controlled study found significant improvements in psychiatric patients with anxiety disorder through use of the stress-reduction component of MVM.⁷⁴ In addition, a previous meta-analysis reported on the distinctive effectiveness of the Transcendental Meditation technique in reducing anxiety compared with other behavioral approaches for stress reduction.²²

Parkinson's disease is chronically progressive with no known reports of spontaneous remission.⁷⁵ Treatment with dopamine mimetics modulates symptoms but is usually time-limited in effectiveness;⁷⁶ therefore, it appears that the short- and long-term improvements in our patient's signs and symptoms are noteworthy. These data are consistent with cohort studies reporting substantial reductions in the rates of serious neurological diseases in long-term participants in MVM programs.^{17,56}

The results of these four cases are generally consistent with epidemiologic findings of reduced prevalence rates (indicated by hospital admission rate) among MVM users for immune-endocrine-metabolic disorders, cardiovascular disease, and neurological disorders.^{17,56} Furthermore, these

initial findings confirm and extend a pilot study of 126 patients in Europe, which reported clinical improvements in several chronic disorders—including diabetes, hypertension, asthma, chronic bronchitis, rheumatoid arthritis, eczema, chronic constipation, and headache.⁷⁷ In this earlier series of cases, patients were treated with several, although not all, of the Vedic modalities used in the current case series.

In terms of a theoretical model, MVM traditionally describes the underlying mechanism of action of these therapeutic procedures as enlivening the body's "inner intelligence."⁷ The latter is proposed to be the fundamental set of organizing principles at the basis of physiological function and structure. The concept of inner intelligence from the ancient Vedic perspective may be similar to Cannon's wisdom of the body.⁷⁸ The common principle is that the body contains an abstract "wisdom" or "intelligence" that coordinates and balances the functioning of the entire physiological system.

Vedic medicine approaches have been proposed to enliven or restore this fundamental level of intelligence in the body. This process, in turn, is proposed to result in the optimizing of innate, homeostatic, self-repair and defense mechanisms and improvements in chronic disease. Because it focuses on procedures to stimulate endogenous restorative mechanisms, the traditional Vedic approach to health may also avoid adverse effects commonly seen with more conventional pharmacologic and surgical interventions.^{7,9}

The knowledge and technologies of MVM are based on the understanding that the orderly structure and function displayed in human physiology is based on laws of nature that also structure and govern the entire physical universe.⁷ MVM includes 40 approaches that derive from the 40 traditional branches of the Veda and Vedic literature.¹³ The different aspects of Vedic literature are classically understood as describing different modes of functioning of natural law; the Veda and Vedic literature as a whole are traditionally held to contain the total knowledge of natural law.¹³ In recent theoretical modeling, Nader⁷ has related these divisions of the Vedic Literature to 40 major systems of human anatomy and physiology. This discovery provides a theoretical framework for the therapeutic strategies of MVM.

For example, MVM therapies may be selected from specific aspects of the traditional Vedic literature on the basis of the correspondence of those aspects with areas of the body involved in the disease process. In selecting Vedic sound therapy for the Parkinson's patient, the clinician chose Vedic sounds that are described as corresponding to functioning of the basal ganglia, particularly the substantia nigra. In this light, it is notable that most of the patients in this study

reported that the Vedic sound therapy component of the program was often associated with immediate and dramatic relief from clinical symptoms. Patients reported such experiences as the following: "During Vedic sound therapy, I experienced profound inner silence and a sense of orderliness in mind and body that seemed the essence of healing. Following each session, my symptoms were clearly reduced." These results are consistent with a recent series of randomized, double-blind, controlled trials on the efficacy of a related Vedic vibration therapy approach that reported immediate and significant improvements in several chronic neurological and musculoskeletal disorders.¹⁴ Nader suggests that the correspondence between the Vedic literature and the areas of human physiology account for these effects.^{7,14} Previous data on effects of music and sound therapy on mental and physical health may be consistent with the posited effects of specific sounds on specific physiological functions.^{37,38}

Findings from earlier studies suggest that some of the mechanisms of the MVM multimodality program are general, that is, through reduction of generalized stress responses (eg, neuroendocrine stress and oxidative stress^{29,45}), whereas other mechanisms may be disorder-specific. Yet, from the traditional Vedic perspective, both general and disease-specific mechanisms are considered interdependent and synergistic.⁷ This concept remains to be more thoroughly tested in controlled experimental settings. Recent recommendations for conventional multimodality treatment and prevention approaches—including lifestyle modification of chronic diseases, such as cardiovascular disease—suggest modern parallels to this traditional approach.

In addition to direct effects on physical disease processes, components of the MVM approach have been shown to have effects on cognitive abilities and mood.⁷⁹ These enhancements may contribute to improved self-care, including adoption of positive health-promoting behaviors and avoidance of negative behaviors.⁸⁰

It is unlikely that the present findings can be attributed to significant placebo effects. Three of the patients in this series had undergone several courses of modern medical therapy before their participation in the Vedic medicine programs. Patients' previous treatments were often intensive in terms of attention and demand characteristics, yet these did not result in sustainable relief from symptoms or long-term objective improvement. Thus, the previous courses of modern medical therapy may be considered as control periods for the study intervention periods in this case series.

In conclusion, it may be noted that Eisenberg et al reported that patients' reasons for seeking alternative or natural medical therapies include "(1) patients are seeking health

promotion and disease prevention; (2) conventional therapies have been exhausted; (3) conventional therapies are of indeterminate effectiveness or are commonly associated with side-effects or significant risk; (4) no conventional therapy is known to relieve the patient's condition; (5) the conventional approach is perceived to be emotionally or spiritually without benefit."^{81(p62)} The present series of cases with a range of chronic diseases, together with the previous literature on individual MVM modalities, suggests the potential of MVM, a traditional and comprehensive approach to natural medicine, to respond to the perceived healthcare needs of selected patients with chronic diseases. Given the social and individual burden of chronic disease in contemporary society,^{1,81} we suggest future research with controlled experimental designs and long-term follow-up to evaluate further the potential effectiveness and mechanisms of these natural medicine programs.

NOTES

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NATURAL MEDICINE

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Divider Title: Hudson

Common understanding
Respect
Shared experience
Basier

1. Should naturopathic medicine in general be accessed and delivered as a stand-alone system or integrated with conventional care and why? Are there medical conditions or situations when this shouldn't be the case? Are there any data to support your position? .

Jore
Hudson

Naturopathic medicine is its own distinct healing art and is best defined by its principles and its therapies. Simply put in modern terms, naturopathic physicians are primary health care providers, family physicians who specialize in natural medicine. The following seven principles are the foundation for naturopathic medicine:

The healing power of nature. (vis medicatrix naturae)

The body has the inherent ability to establish, maintain and restore health. The physician's role is to facilitate and augment this process with the aid of natural, nontoxic therapies; to act to identify and remove obstacles to health and recovery, and to support the creation of a healthy internal and external environment.

First, Do No Harm (primum no nocere).

Naturopathic Physicians seek to do no harm with medical treatment by employing safe, less invasive, and effective natural therapies.

Identify and Treat the Cause (Tolle causum)

Naturopathic Physicians are not only trained to investigate and diagnose diseases, they are also trained to view things more holistically and look for an underlying cause, be it physical, mental, or emotional. Symptoms are viewed as expressions of the body's attempt to heal, but are not the cause of disease. The physician must evaluate fundamental underlying causes on all levels, using treatment that includes treating the root cause rather than just the suppression of symptoms.

Treat the whole person

Health and disease are conditions of the whole organism, involving a complex interaction of physical, spiritual, mental, emotional, genetic, environmental and social/cultural/economic factors. The physician must treat the whole person by taking all of these factors into account. Homeostasis and harmony of functions of all aspects of the individual is essential to recovery from disease, prevention of future health problems and maintenance of wellness.

Physician as Teacher (docere)

The Naturopathic Physician's major role is to educate, empower, and motivate the patient to take responsibility for health. The physician educates about risk factors, hereditary susceptibility, lifestyle habits, and preventive measures that leads to recommendations on how to avoid or minimize future chronic health problems. A healthy attitude, diet, exercise, and other lifestyle habits serve as the cornerstone of our recommendations.

Prevention is the best cure

The ultimate goal of naturopathic medicine is prevention. This is accomplished through education and promotion of life-style habits, and natural therapeutic recommendations. The emphasis is on building health rather than on fighting disease.

Establish health and wellness

The primary goals of the Naturopathic Physicians are to establish and maintain optimum health and to promote wellness. We strive to increase the patient's level of wellness, characterized by a positive emotional state, regardless of the level of health or disease.

In addition to these seven principles, there are two principles that I believe are fundamental to natural medicine, and fundamental to good medicine. *The principle of resonance, and the principle of choice.* Resonance is basically an issue of compatibility. Which approach-nutrient, herb, pharmaceutical or any substance is compatible with this particular patient in this particular moment and set of life circumstances. The selection of the therapeutic approach that is resonant with the individual is the therapy that will create the most healing momentum. Picture a child on a swing. You stand behind the child pushing them forward so they can achieve the most momentum so that swinging becomes effortless. If you push them at the right moment, your force is perfectly timed with their body motion and the rhythm of the swing. The perfect timing sends them smoothly and easily higher and with the slightest of effort, they keep swinging forever. If you push them at the wrong moment, the swinging becomes jerky, they lose speed and height, and the rhythm is disrupted. It then takes a great deal of their effort to regain their momentum, speed and height. The perfect effortless swing comes from the perfectly timed and perfect forcefulness of the "push". This is resonance. The person with the health problem is the child on the swing. The person who pushes the swing is the physician and the therapy they use. Any medicine, natural or pharmaceutical can be resonant. The art of medicine is to know when to use what, in whom, and for how long. I believe the most profound healing principle in the practice of medicine is the principle of resonance. Not whether the medicine is natural or synthetic, alternative or conventional; not "Naturopathic" philosophy vs. conventional "allopathic" philosophy. The healing method is the medicine that is right for that person. The true goal of a physician is to perceive what is resonant with that individual.

My second guiding principle is that of choice. The patient chooses what is right for them. It's not my principles, or a rigid philosophy, or a system that does something to the patient. Education about the options, education about the health problem, education about recommendations including their pros and their cons, and sharing resources, all provide the context in which the patient can make an informed decision. The physician must be perceptive, listen, investigate, evaluate, education, offer recommendations, and then create an environment where the individual can make a decision for themselves. The individual seeking my help gets to choose. It may be black cohosh or it may be estrogen replacement therapy. It may be a rigorous naturopathic health regime, or it may be surgery. It may be an integrated combination, a "complementary" approach using the best of two worlds. Choice is a powerful force. The force of individual responsibility, empowerment, self direction. Choice fosters will, desire, discipline, motivation. Freedom of choice occurs in an environment of equality and respect between physician and patient.

These two principles, resonance and choice, are fundamental aspects of an integrated health care model. We can no longer "afford" a fractured approach to health and healing where alternative medicine is on one side and conventional medicine is on the other. There is a spectrum of options that go from simple to complex, from the least intervention to the most aggressive intervention, and from the most natural therapy to the most synthetic or technological. We need all of it. Human intelligence has created incredible tools and techniques.

The physician who is educated and aware of all the options and is aware of the talents and scope of practice of other health care disciplines is the key to an integrative model of health care. This physician must learn to understand how and when best to use all these choices on behalf of someone who is ill and suffering. An integrated model incorporates the natural/ naturopathic perspective and the conventional perspective and knows the strengths and weakness of each in different circumstances. When we can do something effectively and safely with nontoxic, natural medicines with far fewer side effects, and more cost effective, then what would stop us? If we can't, or it's too risky in terms of clinical sequelae, then we use therapies that are more aggressive or more invasive; medicines with more side effects but may work better or be a more appropriate choice because the risk of the disease is greater than the risks of the treatment.

Naturopathic and other alternative medicine disciplines have their strengths and their weaknesses. Conventional medicine has its strengths and weakness. I encourage consumer, practitioner and legislator to advocate for practitioners of all disciplines to integrate our intelligence, experience, and energies and build cooperative working relationships with each other so that we can truly help people to choose what works best for them.

When considering an integrative model of health care, we do not mean that any one discipline tries to take on the skills and role of all. We are not talking about conventional medicine dabbling in herbs or supplements or other natural therapies. Nor are we talking about naturopathic physicians expanding their scope of practice beyond their fundamental principles. What we are talking about is health care disciplines working more closely together- in medical schools, clinics, hospitals and research settings, to do a better job at disease prevention and medical treatments. We need to understand better the synergistic effects of different modalities as well as some of the contraindications for combined therapies. Drug-herb and drug-nutrient interactions can be both positive and negative.

The Naturopathic Physician is actually in the ideal position to be the triage practitioner for an integrative medicine system. Naturopathic Physicians are the most eclectically trained of all practitioners: Basic sciences, Clinical Sciences, Pharmaceuticals, Nutrition, Botanicals, Physical medicine, minor surgery, lifestyle counseling, and counseling in general. Naturopathic Physicians best understand all of the specialties in medicine-both conventional and alternative, as well as the primary care disciplines. This broad eclectic education and practice is unique amongst all health care practitioners.

Although I think Naturopathic Physicians are in the best position to be the gate-keeper of an integrative model, I don't expect that would be feasible given the political obstacles. What is feasible though, is to create more venues and opportunities for intentional co-management between conventional and alternative practitioners. The potential is great:

- Increased health care consumer satisfaction
- New medical treatments
- Healthier Americans
- Improved outcomes
- Disease reduction through greater prevention efforts
- Reduction in medical costs

2. Should naturopathic health care for women be accessed and delivered as a stand-alone system or integrated with conventional care and why? Are there medical conditions or situations when this shouldn't be the case? Are there any data to support your position? Is there a documented patient preference for a stand-alone or integrated approach to naturopath women's health care?

Modern women are the first women in history to enjoy the luxury of anticipating that their lives will be healthy, long and self-directed. This awareness of opportunities and choices often leads them now to seek the benefits of natural medicine in ever-increasing numbers. More dominant and discriminating consumers of health care than men or children, and sooner to grasp the advantages of a vitalistic holistic healing art, their innate wisdom has already led to many significant changes in conventional medicine in recent years. Women insist on "natural childbirth" and now it is the goal of most pregnant women and available everywhere. They have too long felt the restrictions of paternalistic conventional medicine with its uniformity and lack of individualization of healing approaches, and are therefore more than ready to embrace natural principle of "treating the individual". Moreover, the success of natural treatments in relieving disease and suffering has done much to effect its popularity. The now well-recognized neglect of women in allopathic conventional research and the failure to prioritize women's health in general, has left a profound gap in health care which alternative medicine is well poised to fill.

Women want safe, effective, affordable medicine. Women want to be educated about their bodies and their health. Women want to make choices in their health care that they have determined is right for them. By philosophy, by design, and by commitment, alternative healing systems have the package to offer women what they want.

Beginning with the AMA's exclusion of women in the late 1800's, orthodox medicine's lack of respect for women both as healer and patient has been all too obvious. Today, significantly more empowered women have come to reject the dictums of orthodox medicine in greater numbers. Women intuit the limitations of the bio mechanical model to completely explain physiological processes. Despite the orthodox physician's uniform advocacy for menopausal hormone replacement therapy for all, only a fraction, less than 20% of women comply; 90% of the women who begin HRT, stop within the first year of use. Partially a failure of access, it is a profound testimonial to their lack of trust in conventional medicine's safety and efficacy and commitment to their well-being.

The creation of synthetic hormones in the 50's and 60's was unquestionably revolutionary for women in that it suddenly allowed personal life autonomy through successful fertility control, and they no longer suffered the hot flushes and mood swings of menopause. Women's lives were changed forever. However, hormones coming as they did on the heels of the "miracle medicine era" in which antibiotics and vaccines led the general public to believe medicine could do no wrong, and the consequence of hormone excess and side effects were not anticipated nor quickly recognized and dealt with. And still today, most conventional practitioners will recommend a postmenopausal lifetime of HRT while the data has begun to clearly show that the risk of breast cancer increases after 5 years of use. Consequently, many women distrust and fear hormonal medicine and their conventional physicians. Unfortunately, this fear and mistrust then leads to the denial of a medicine (HRT) that in some cases may achieve more benefit than risk. Here's where the integrated wisdom and approach comes in. While clearly not a panacea, hormones are not all bad and have important uses in selected individuals. We can also use a combination of a reduced dose of hormones along with soy and herbal medicines to bring about the most benefit with the least risk.

The experience of witnessing the pros and cons of hormonal manipulation and declining the conventional medical establishment's extensive reliance on hormones has resulted in women insisting upon participating in their health care decisions in a way conventional medicine is just beginning to recognize. I believe that the baby boomer menopausal woman is having and will continue to have a more significant impact on our health care model than any other previous group of health care consumers. Menopausal women today reject the notion of a single therapeutic modality being essential for all women undergoing a natural process. They reject the notion of taking a drug for the rest of their life, especially if they have other options, especially if they can do other things to help prevent osteoporosis and heart disease, and especially if that drug increases their risk of a life threatening disease.

Women are the biggest consumers of health care in America. A recent menopause supplement to the Journal of the American College of Ob-Gyn, OB-GYN states, "focus groups, involving women age 40-60, reveal that women know more about herbal medicines than about estrogen..." That seems an impressive testimonial to the power of alternative medicine in its alliance with the natural wisdom of women to define their own health care standards. It is an invitation to alternative medicine to continue to provide women with the wider, healthier, options they seek. Fifty percent of American women will be menopausal by the year 2015, and they will provide alternative medicine the greatest opportunity yet to serve our communities.

In addition to practitioner-delivered natural health care, natural medicine offers safe and effective self-care options for many common conditions such as vaginitis, PMS, fibrocystic breast disease, menopause, bladder infections, and more, further expanding women's health care autonomy. I support the self-care approach to healing. Much of the practice of medicine is not particularly difficult or complex. Education and resources can provide a lot of very practical information. One of the things I've tried to do in my book ([Women's Encyclopedia of Natural Medicine](#)) is not only provide some treatments that someone can use for themselves, but provide guidance as to the importance of seeing a licensed health care practitioner and giving some guidelines about when self care is not appropriate. Health care is a team approach. The patient, the practitioner, the therapies. The team can include the alternative and the conventional practitioner; and better still, ones that talk to each other on behalf of the patient.

The importance of choice in doctors, medical approaches, involvement in the health care process, adopting healthy lifestyles, and safer nontoxic natural therapies are recognized by today's woman as essential to health and well being. Women highly value the longer time spent in discussion with alternative providers as well as having her history collected carefully, completely, and respectfully. They value processing their options thoroughly and individually. This unique quality of alternative health care systems is rare in conventional medicine and one of the chief reasons women seek our care.

Naturopathic Physicians and other providers of alternative medicine must seek to verify the "scientific" truth of our medicines whenever possible—by research, and by modifying the mechanistic model when necessary to suit our vitalistic philosophy. We must continue to stand by our tradition of resonance between patient and therapy—ever seeking the resonance for a particular woman with a particular problem at a particular time in her life.

Lastly, alternative medicine must recognize that conventional medicine, while inadequate alone, is here to stay, and offers important options and life saving measures. Likewise, conventional medicine must recognize that natural therapies are a fundamental healing tradition of all cultures, and that modern alternative medicine is also here to stay. The more we make ourselves aware of them, the better we can guide women in selecting from all options, both alternative and conventional. A combined, well-thought out cooperative and integrative approach is often the best that medicine has to offer. Our open-mindedness will be rewarded many fold by the improved health of women and their increased satisfaction and trust in their health care providers.

3. Based on your experience, what policy recommendations do you have for the Commission?

- Expand funding for the National Center for Alternative and Complementary Medicine
- Provide research dollars and directives for integrated multi-therapeutic interventions
 - (See list below: menopause, osteoporosis, heart disease, etc)
- Provide Medicare and Medicaid reimbursement for services rendered by all licensed alternative providers
- Provide support for pilot projects at conventional and alternative medical schools for departments in integrative medicine
- Fund development of educational brochures on an integrative approach to
 - Menopause
 - Osteoporosis
 - Heart disease
 - Diabetes Mellitis
 - Breast Cancer
 - PMS
 - Fibrocystic breast
 - Infertility
 - Vaginal infections
 - Endometriosis
 - Uterine fibroids
 - Depression
 - Anxiety syndromes
 - Insomnia

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SUMMARY OF REMARKS BY ROBERT M. DUGGAN FOR PRESIDENTIAL COMMISSION
HEARING ON TUESDAY, DECEMBER 5, 2000

November 29, 2000

Members of the Commission:

Thank you for the opportunity to speak with you. I'm deeply honored. I'm delighted that this Commission was created. I have great hopes for the policies you will recommend.

You asked that I address three questions. The first two:

- 1) "Should acupuncture be accessible and delivered as a standalone system, or be integrated with conventional medical care?"
- 2) "Should traditional acupuncture be accessible and delivered apart from, or in conjunction with, other modalities of Oriental medicine?"

These questions bring up more fundamental, philosophical issues about what is complementary and alternative medicine. What is healing? What is medicine? What is this huge popular movement that has occurred in the United States and around the developed world in the past 30 years? – This social change that has led to the creation of this Commission.

I have practiced acupuncture now for almost 30 years. I began my studies in England in 1971. I am the President of a graduate school with 225 full-time graduate students who spend three years studying traditional acupuncture. More than half of those students already hold a graduate degree. Of our 700 graduates, 84% of them are earning a very comfortable living at a rate significantly above the national average for acupuncture practitioners. We have a 10-year zero default rate among our graduates with regard to Federal student loan repayment. Students come from all over the United States, and we always have a few from overseas. We have just received authorization from the State of Maryland to develop a similar three-year program for Botanical studies and a separate two-year program in the Art of Healing. **Our students are trained, not only in acupuncture skills, but also in the Art of Healing.**

I point to my length of experience and the size of the Institute and our new authorizations to illustrate that there are really **two worlds of CAM and, I believe, two worlds in all of medicine in the United States today:**

There is the world of technique and modality – the competition over which modality, acupuncture, herb, or Western medicine, is better. **The search for the magic bullet** or for the technique that is effective, regardless of the individuals involved.

I believe **there is another world** that is the world driving the public's involvement that **focuses on the Art of Healing. That is the world of the public recovering their own empowerment.** They are recovering their own ability to be in touch with their own wellness, to understand their symptoms, to learn their own ways to wellness. Two or three phrases from our research: "Oh, yes, I still have the hip pain and I'm better in myself.", or, "Asthma has become my teacher. I used to be in and out of the hospital all the time. I am now aware of how I tend it myself."

With the guidance of a wonderful anthropologist, Claire Cassidy, **we've done two separate studies, all of which point to the fact that the public is buying a unique product, the Art of Healing, which focuses on their sense of healing empowerment.**

To come back to your two questions:

To the first: Of course, **acupuncture should be accessible, both alone and integrated.** My private practice that is not dependent on insurance and I keep many individuals out of the sick care system, and my pro bono work in inner-city Baltimore with one patient, alone, probably saved the local emergency room more than \$100,000 by effectively teaching him what became obvious. On the other hand, I find it absurd that there is not acupuncture as an emergency care in every shock trauma unit, and I'm shocked that everyone with a stroke does not automatically receive basic acupuncture as part of their recovery. And, I'm shocked that acupuncture is not more widely available for everyone involved in the issue of healing from addiction. And, there is sufficient research for all this to have translated into best practices by this date. And, **all this should be covered because it restores wellness and breaks up the cost-quality-access conundrum.**

And, the second question: **Acupuncture and Oriental medicine – of course, they should be separate and integrated. Only the Western mind tends to ask either/or questions. The very philosophy of most cultures is a both/and.** Acupuncture is unique and distinct in itself, historically, and in modern practice. It might be said that it would take 10 years for anyone to have basic mastery of acupuncture before thinking of mastering herbs or the martial arts or the body/work or diet. And, of course, this should be used in an integrated manner in the way that I work closely with physicians, surgeons, chiropractors, and herbalists in my practice.

The basic implication of my answer to both of these questions is that we are moving from a linear world into a complex world where the patients know much more than the providers, where they become highly educated, where they understand their symptoms, and where they work collaboratively. I become very upset when I go to acupuncture and CAM meetings where there is a conversation about who is the "primary care provider". **The patient is the primary care provider. We will only shift the cost quality access dilemma of our healthcare system when we understand that, by making the patient the primary care provider, will we move 70% of visits out of the sick care system and place them in a wellness culture.**

Your third question: "What policy recommendations do I have?"

- 1) As a professional acupuncturist, and as President of an Institute tending the welfare of my graduates, **I would recommend to you that you would expand insurance coverage for acupuncture – that acupuncture be included in Medicare, Medicaid, and the other forms of reimbursement.** However, I am also aware that while that should be done to make it accessible, **I also want to be careful that we not turn CAM/acupuncture into a modality where more of the modality is better and, so, the costs go up, and the dependency of the patient increases. Careful consideration should be given to the self-responsibility aspects of medical savings plans versus insurance reimbursement.**

Other policy recommendations reflect this philosophical perspective.

- 2) Support CAM training that focuses on **relationship centered healing** and the art of teaching people how to be empowered in their own wellness.
- 3) Create a **new agency to deal with the quality of herbal products.** This agency must understand the philosophical, scientific, and economic issues of herbal medicine. This cannot be done by the FDA. **Allocate funds from the tobacco settlement to the growing of high quality herbal products on the land being removed from tobacco production** and incentivize the transfer of those lands into organic farming.

- 4) Support the training of acupuncturists and other CAM providers through the **Federal student loan forgiveness program in return for the work by these practitioners in deprived areas**. This Bill is currently under consideration in Congress.
- 5) Create policies that encourage **one-half day per week "pro bono" service by all CAM practitioners** for communities in need.
- 6) Promote **CAM and wellness education in grade school, middle school, and high school** – this is where the foundational concepts are formed and, at the moment, they often foster dependency rather than awareness of how one heals oneself.
- 7) Research outcomes often do not cross over into clinical practice. Support initiatives that **enable the outcomes of CAM research to be transferred into clinical practice**.
- 8) Promote **research on quality of life outcomes** rather than research on the mechanism of various technologies. It may be centuries before we understand mechanism as we shift from a biochemical world to a biophysics world.
- 9) **Educate all health related professionals** from nurses aides, to herbalists, to surgeons, **in the recovery of "bedside manner" and the healing relationship** (reference – the Pew Trust Initiative on Relationship Centered Healing).
- 10) **CAM policy should be strongly linked to supporting hospice, to palliative care, and to ways of enabling people to home care**.
- 11) Reground healthcare in **"grandmother's/kitchen table wisdom"**. There was a Harvard study that reported poor Hispanic women with little access to healthcare had some of the best outcomes in childbirth. We must have policies that **encourage hospitals and the many State Departments of Health to support "indigenous" grandmothers' ways of wellness**.
- 12) **Distinguish wellness education** as an end in itself as distinct from preventing future disease.

I thank you.

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- 12) **Distinguish wellness education** as an end in itself as distinct from preventing future disease.

I thank you.

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VI

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SESSION VI:

CAM Integration

in Existing Delivery Systems

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SAMHSA: *Trachtenberg*

Catholic Health Initiatives: *Hammerly*

Speakers' Questions for Session VI:
CAM Integration in Existing Delivery Systems
2:30 p.m. - 4:00 p.m. on Tuesday, December 5.

1. Briefly describe your programs (no longer than one page per program), including the CAM services provided. What is was the rationale used by your organizations for integrating those services rather than more conventional approaches?
2. Provide any cost/clinical effectiveness data to compare results of CAM services with conventional approaches that had been used in the past, or are offered still for similar health conditions.
3. What are the barriers and obstacles that your organization faced during integration, and how are you overcoming those challenges?
4. If possible, enlarge your discussion to include your knowledge of other organizations like yours. In your view, what are the common barriers and obstacles faced by such organizations when integrating CAM services? What opportunities to integrate CAM services are not being taken and why?
5. What recommendations would you make to facilitate the integration of CAM services in organizations such as yours?

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Trachtenberg
Divider Title: _____

Testimony to the White House Commission on behalf of the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA)

by

Alan Trachtenberg, MD, MPH, Medical Director, Office of Pharmacologic and Alternative Therapies (OPAT/CSAT/SAMHSA; atrachte@samhsa.gov; 301-443-1281)

It is a pleasure and an honor to participate in this meeting of the White House Commission on Complementary and Alternative Medicine Policy. My name is Alan Trachtenberg. I am Medical Director of the Office of Pharmacologic and Alternative Therapies (OPAT). I came to this agency after 7 years at NIH, where, among other things, I directed the OAM from 1994 to 1995 and also organized the NIH Consensus Development Conference on Acupuncture in 1997. It is particularly appropriate for CSAT/SAMHSA to be presenting at this meeting that focuses specifically on access and delivery of services, particularly in a session on integration in delivery systems. The Substance Abuse and Mental Health Services Administration (SAMHSA) is the primary USPHS agency responsible for federally funded mental health and substance abuse services. A vital part of our mission is the full integration of these services with the rest of this nation's public health and medical care systems.

On November 28, the Center for Substance Abuse Treatment released a report under its National Treatment Plan Initiative, *Changing the Conversation*, which reflects the very best thinking in the treatment field for alcoholism and drug addiction. This report highlights the stigma and discrimination faced by Americans with addictions (and their treatment providers). So we share many of the resulting difficulties, such as prejudice and outdated ideas, in common with the field of alternative therapies. In fact, one of the mainstays of treatment in substance abuse, self-help groups like Alcoholics Anonymous and other 12-step programs, was even included as an alternative therapy in Eisenberg et al's original grouping of these.

Within SAMHSA we have three Centers: the Center for Mental Health Services (CMHS), The Center for Substance Abuse Prevention (CSAP), and the Center for Substance Abuse Treatment (CSAT). The bulk of my office's activities at CSAT are currently involved with taking over from FDA in the regulation and oversight of opiate addiction treatment practitioners. These include the kind of clinics in which the Yale group (Avants et al), that recently published in the Archives of Internal Medicine, performed their excellent and highly significant (both statistically and historically) randomized trial of ear acupuncture for cocaine addiction. Since basic treatment of opioid addiction with agonist medications such as methadone is highly effective against heroin addiction but has little activity against cocaine, this kind of clinic offered the perfect setting for testing an innovative treatment against cocaine. The bulk of SAMHSA's alternative therapies activities come through the Center for Substance Abuse Treatment, and that is what I will be speaking about today.

SAMHSA, and specifically CSAT, encourages grant applicants to submit innovative proposals for treatment programs to be culturally competent, comprehensive and community oriented. These

are goals we feel are appropriate for any center claiming to provide community oriented primary care. To the degree that these goals may be facilitated by the inclusion of alternative or traditional healing practices (healing practices based on cultural traditions), then the inclusion of such practices is actively encouraged. For instance, a grant program for rural, remote and/or culturally distinct populations was begun by CSAT's Division of Practice Systems and Development (DPSD) as far back as 1993. SAMHSA's leadership in this area is demonstrated by the fact that this actually preceded any of the grants that came from the NIH Office of Alternative Medicine (OAM). The treatment programs funded under these grants incorporated a variety of traditional practices including acupuncture, sweat lodge, traditional Hawaiian medicine and other culturally specific healing practices. From 1993 through 1998, these programs received an annual total of \$4.5 million per year from CSAT. Since then, having demonstrated their utility, most of these programs were picked up by their states, and continue to be funded by block grant dollars, CSAT targeted capacity expansion grant funding and/or other public resources.

Currently, the occasional proposal that includes an alternative component, is being treated just like any other proposal. The grants that are funded by CSAT are primarily driven by local community needs, and some applicants state a need for the inclusion of acupuncture or a culturally specific healing practice. Obviously, we must be assured that the practices are safe. They are generally inexpensive. We do require that such components be integrated into a comprehensive palette of services. We are generally not interested in funding stand-alone alternative therapies.

Part of the reason for our insistence on a comprehensive approach is the same as our justification for including alternative therapies in the first place, even though they may not have yet had their efficacy proven adequately. This justification is the well replicated observation in drug abuse treatment that the amount of time spent by a patient in therapeutic settings is one of the most important determinants of long-term outcome. So the number of weeks or months in treatment and the number of hours or days per week is a key, often the single most important, independent variable predicting better outcomes. Knowing this, alternative therapies can be seen as a form of social marketing or outreach for community oriented treatment programs. Since anything that (safely and inexpensively) brings a patient through the doors and keeps them coming back to the treatment setting is beneficial, almost any safe, inexpensive and popular treatment adjunct that can do this will contribute to beneficial treatment results.

This is certainly at least part of the apparent benefit of acupuncture that was demonstrated by Schwartz, Saitz, Mulvey and Brannigan in a study funded by CSAT and published in the Journal of Substance Abuse Treatment (1999). I have attached a copy of that paper to this testimony. Schwartz et al, using a multivariate model on retrospective cohort data from Boston, showed that patients choosing outpatient programs with acupuncture were less likely to relapse in the six months following discharge than were patients who had chosen residential programs.

While it may be difficult to gain the highest level of evidence to support these practices, there is still considerable room to demonstrate their apparent benefits for patients of the programs that

incorporate them. CSAT's Treatment Improvement Protocol (TIPS) Series, has often included advice based on the consensus from panels of experienced clinicians as well as on the available scientific data. This makes the TIPS much broader and more generally useful to clinicians, whose patients may not happen to have problems that have already been fully investigated by the research community.

At this time, CSAT is evaluating the possibilities for assembling a consensus panel to make recommendations about how acupuncture could be usefully incorporated into drug abuse treatment programs. Such an effort would be an obvious next step, to follow up on the 1997 NIH Consensus Statement on Acupuncture, which said (in part) that "Acupuncture treatment for many conditions such as asthma or addiction should be part of a comprehensive management program." My personal view is that the treatment guidelines to come out of such a process would be most likely to include the acupuncture protocols of the National Acupuncture Detoxification Association (NADA). This is the "ear acupuncture in a group setting" approach developed and popularized by Dr. Michael Smith and his colleagues at Lincoln Hospital (Bronx, NY) and used by over 400 drug treatment programs, 40% of drug courts and by almost all addiction researchers who study acupuncture in the USA.

At the recent annual meeting in Boston, MA, of the American Public Health Association (APHA), CSAT co-sponsored one of the scientific sessions conducted by the Alternative and Complementary Health Practices (ACHP) Special Primary Interest Group (SPIG). This was a session on ACHP in drug abuse treatment and the papers presented there included a range of alternative therapies including acupuncture, meditation, homeopathic and herbal approaches, all of which were reported as being provided in an integrated fashion with conventional therapies. CSAT staff were also instrumental in organizing a session jointly sponsored by the ACHP-SPIG and the APHA Science Board titled "The Science of Alternative Medicine." Speakers at this landmark session (the Science Board seldom sponsors individual sessions at the annual meeting) included Herbert Benson, MD (author of *The Relaxation Response*), Ted Kaptchuk, OMD (author of *The Web That Has No Weaver*), and Lawrence Kushi, DSc (A nutritional epidemiologist whose family contributed memorabilia to the Smithsonian Museum to form the "Kushi Family Collection on Macrobiotics and Alternative and Complementary Health Practices."

CSAT's discretionary grant programs, such as the program for Rural, Remote and Culturally Distinct communities,(described above), make up a very small (however essential) portion of our total budget. The vast majority of CSAT's budget goes into the State block grants for substance abuse prevention and treatment (SAPT), which go annually to each state, based on a formula mandated by our authorizing legislation. Disbursement of block grant funds is largely under state control, but we do know of specific instances where programs funded by SAPT block grants have been using aromatherapy, relaxation and/or meditation techniques and, of course, acupuncture. We also know of SAPT block grant funded treatment programs serving Native American populations that offer sweat lodge ceremonies, smudging, vision quests or other native practices traditional to the community being served.

Since the spending of a majority of CSAT's budget (ie. the SAPT block grant) is determined by the States, we are currently working with the National Association of State Alcohol and Drug Abuse Directors (NASADAD) to ascertain the range and frequency of alternative therapies being practiced and/or requested by programs funded with block grants, as well as other sources of public funding. NASADAD held a one-day conference on "Traditional, alternative, and complementary approaches to the treatment and prevention of substance abuse" on June 3, 2000. The conference took place in Reno, Nevada, and was held in conjunction with the regular, annual NASADAD Meeting (June 4-6, 2000). CSAT's Office of Pharmacologic and Alternative Therapies sponsored this June 3rd conference and subsequent NASADAD activities in this area.

The objective of the conference was to provide a forum for discussing the use of alternative therapies and how they might be integrated into addiction treatment programs. There were presentations on current research and the integration of acupuncture, botanical applications, and transcendental meditation in the treatment of addictive disorders. Thomas Kiresuk, PhD, Director of the Center for Addiction and Alternative Medicine Research, in Minneapolis, provided an overview of current scientific research. Steven Stepto, MD, MPH, who practices at the 14th Street Clinic in Oakland, California, and San Francisco's Native American Health Center, spoke about the use of acupuncture in the reduction of craving and other aspects of treatment. John Kolenda, President of the National Acupuncture Detoxification Association (NADA), described the NADA protocols for auricular acupuncture in addiction treatment. A hands-on presentation on botanical applications was provided by Ethan Nebelkopf, PhD, Director of the Family and Child Guidance Clinic at the Native American Health Center in Oakland, California. Raju Hajela, MD, President of the Canadian Society of Addiction Medicine, discussed the benefits of Transcendental Meditation.

As we expected, NASADAD found that the alternative therapy being mentioned most often by State Directors was acupuncture. In New York State alone there are 174 treatment programs currently providing acupuncture. This is about 20% of the programs in that state. Program staff from Virginia estimated that one third of the drug programs in their State offer acupuncture. Acupuncture is said to have helped inmates to dramatically reduce their violent behavior in the Denver City jails. SAMHSA's own Uniform Facility Data System (UFDS), found that 4.8% of addiction treatment programs surveyed in 1997 (meant to be a complete survey of all drug treatment programs in the US) were providing acupuncture. This did not change significantly in the 1998 survey. NASADAD will be attempting to consult the rest of their membership for their input. This will help guide the next generation of CSAT demonstration projects or other specific activities in the field of alternative, complementary and/or traditional health practices.

Finally, to summarize material from my more comprehensive but circuitous answers above, I will synopsise brief and direct answers to the questions most directly articulated in the Commission's letter of invitation to me:

> 1. What CAM products and practices does your Agency support? How, why, and by whom were they selected? Where, how, and by whom are they provided?

A: We support a variety of alternative practices as elements that may be included as parts of comprehensive treatment programs. These elements include acupuncture, meditation and culturally specific healing practices such as sweat lodge and traditional Hawaiian medicine. The specific practices are chosen based on needs as determined both locally and/or at the State level. Because most CSAT funds are provided directly to the States, in the Substance Abuse Prevention and Treatment (SAPT) block grants, we are working with the National Association of State Alcohol and Drug Abuse Directors (NASADAD), to gain a more complete picture of the alternative therapies used in programs funded by CSAT/SAMHSA as well as other public funding sources.

> 2. What has your Agency done to make the access to and delivery of CAM products and practices more culturally and linguistically appropriate?

A: Alternative therapies and traditional healing practices have been included in CSAT funded programs primarily as elements of culturally relevant, comprehensive, treatment and outreach or even as part of basic cultural competence, for instance, in programs served by grantees of CSAT's Rural, Remote and/or Culturally Distinct grants program. The cultural and linguistic appropriateness of the specific alternative or complementary health practices for communities served by these grantees is itself the primary impetus for their inclusion by the specific programs who incorporate them.

> 3. Is the delivery of CAM products and practices to your Agency's target populations accomplished as a stand-alone system or integrated with conventional care and why?

A: All therapies for drug abuse treatment, be they alternative or conventional, psychodynamic or medical, should be included in an integrated matrix of services that should be made as comprehensive as possible and tailored to the specific needs of the patient and his or her community. In the field of substance abuse treatment, we recognize that many elements of our treatment programs (like so many conventional medical practices) are based on somewhat less than perfect evidence. However, we do have much evidence that our patients' clinical outcomes improve in association with increasing amounts of time spent in treatment settings. If an alternative therapy brings patients into the treatment setting and keeps them coming back a bit longer, it may therefore have utility over and above whatever specific efficacy it may have. This would not be the case for a single, stand-alone therapy, be it alternative or conventional.

> 4. What does your Agency need to improve access and delivery of CAM products and practices to its target populations?

A: In the field of substance abuse treatment, we have developed a well integrated model, which

the rest of medicine could well benefit from following. It is comprehensive, culturally competent and community oriented. Ear acupuncture detoxification, which was originally developed as a alternative treatment for opioid agonist pharmacotherapy, is now augmenting pharmacotherapy treatment for patients with coexisting cocaine problems. The advocates of acupuncture have joined with the advocates of opioid agonist pharmacotherapy to create a more holistic synthesis. Each has contributed to the success of the other, both clinically and in public perception. And ideally, all of this is built on a broad base of psychosocial support for the patient and their families. This support can include culturally specific healing practices, when these are relevant to the patient's family and community. Acupuncture may have started as a culturally specific healing practice, but is now a trans-cultural therapy, requested by and helping patients from a broad variety of backgrounds.

Dr. Nelba Chavez, SAMHSA's Administrator, has pointed out that "Although the current treatment gap is not precisely known, clearly it is wide. Of the estimated 13 million individuals in need of alcohol and drug treatment, approximately 10 million are not receiving it." Of the people who are "in treatment," many may have no access to the most appropriate treatment for their condition or may face limits on length of stay that inhibit treatment effectiveness. Sufficient public and private resources must be available and appropriately deployed to deliver the quantity, the types, and the levels of care needed. Quantity should be understood to combine frequency, duration, and intensity of treatment. For certain groups, such as people in rural areas, women and Native Americans, the problem is especially acute. CSAT's National Treatment Plan addresses national treatment needs on a comprehensive basis, and I recommend it to anyone with an interest in public health. I have brought a copy with me today, and the National Treatment Plan documents can be accessed on line at www.natxplan.org.

I am very grateful to the Commissioners and their staff members for today's opportunity to come and speak with you about CSAT/SAMHSA's activities in this area of such great public interest and even greater public health relevance.

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ARTICLE

The Value of Acupuncture Detoxification Programs in a Substance Abuse Treatment System

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Abstract—Our purpose is to compare baseline characteristics and detoxification readmission rates of clients treated at outpatient acupuncture programs and at short-term residential programs, two options available to persons seeking substance abuse detoxification. This was a retrospective cohort study using data on clients discharged from publicly funded detoxification programs in Boston between January 1993 and September 1994. Multivariate models were used to examine the effect on 6-month detoxification readmission rates of treatment at residential detoxification programs (used by 6,907 clients) versus at outpatient acupuncture programs (used by 1,104 clients) after adjusting for baseline differences. Acupuncture clients were less likely to be readmitted for detoxification within 6 months (odds ratio [OR] 0.71, 95% confidence interval [CI] 0.53–0.95). Similar results were found when the analysis was performed on a subsample of clients that were relatively similar in terms of baseline characteristics (OR 0.61, 95% CI 0.39–0.94). We determined that acupuncture detoxification programs are a useful component of a substance abuse treatment system. © 1999 Elsevier Science Inc. All rights reserved.

Keywords—acupuncture; detoxification; substance abuse treatment.

INTRODUCTION

THE ROLE OF acupuncture in substance abuse treatment is controversial. A National Institute on Drug Abuse panel

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that met in 1991 concluded that "A review of available data indicates no clear evidence that acupuncture is effective compared to placebo or to existing treatments in the detoxification, primary rehabilitation, or relapse prevention of opiate or chemical dependence" (McLellan, Grossman, Blaine, & Haverkos, 1993, p. 575). Despite this, "ear acupuncture for substance abuse is used on 5,000 patients daily in literally hundreds of different settings in the United States and Europe" (Smith, 1994, p. 587), perhaps reflecting the fact that acupuncture has not "been proven ineffective in the treatment of substance dependence" (McLellan, Grossman, Blaine, & Haverkos, 1995, p. 141).

There have been several small randomized trials comparing outcomes of those exposed to sham versus real

manual auricular acupuncture, most of which have suggested some value from acupuncture (Bullock, Culliton, & Olander, 1989; Bullock, Umen, Culliton, & Olander, 1987; Lipton, Brewington, & Smith, 1994; Washburn et al., 1993), though not all (Worner, Zeller, Schwarz, Zwas, & Lyon, 1992). Studies such as these attempt to isolate the value of acupuncture when added to other program components. We are not aware of any studies that have compared entire programs that include acupuncture as "an adjunct or a complement" to other program activities (the way in which acupuncture is viewed by its supporters; Brumbaugh, 1993) to alternative treatment modalities.

The need for well-designed randomized controlled trials of acupuncture programs is indisputable. Nevertheless, the report by the Quantitative Methods Working Group convened by the National Institutes of Health (NIH) in support of the NIH Office of Alternative Medicine (Levin et al., 1997), while recognizing that "for alternative therapies to become accepted, they must endure the same degree of scientific scrutiny as conventional therapies" (p. 1092), also notes that "clinical trials are not the only game in town" (p. 1087) and that "in fact, new medical knowledge most often is obtained through observational means. . . . This is typically an important first step in understanding an effect on a particular outcome of a previously unconsidered factor" (p. 1089).

Our focus in this article is on the benefits of outpatient acupuncture detoxification (detox) programs as a component of a substance abuse treatment delivery system, where, for those seeking detox, it is an alternative to traditional short-term residential detox. Observational studies are particularly useful for examining alternatives in a field setting. This is the design used in our study of clients seeking detox through the publicly funded substance abuse treatment system. We compare characteristics and 6-month readmission rates for detox of those who were initially treated in an outpatient acupuncture program to those initially treated in a short-term residential detox program.

Outpatient acupuncture programs usually combine acute detox with longer-term maintenance and motivational counseling over several months; short-term inpatient residential detox programs, which last around a week or less, medically treat short-term withdrawal symptoms and then refer clients to further inpatient, outpatient, or self-help treatment. These are very different treatment modalities. However, as part of a substance abuse treatment system in which clients seeking treatment present at intake sites for assessment and referral, outpatient acupuncture programs are an alternative to short-term residential detox programs. At the point of entry, a decision must be made—is the client referred to an acupuncture program or a residential detox program? These alternatives at the time of entry into the system provide the rationale for our comparison of clients treated at acupuncture programs to those treated at short-term residential detox programs.

It is important to emphasize at the outset that the purpose of our analysis is not to isolate the value of the technique of acupuncture per se, but to compare outpatient detox programs that include acupuncture to short-term residential programs, the detox modality most commonly used in the publicly funded treatment system.

METHODS

Sample

Boston was one of the eight Target Cities demonstration projects funded in 1990 by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA) to design and implement enhancements to the publicly funded substance abuse treatment system. (By publicly funded, we mean programs receiving federal or state funds, in our case which flow through the Massachusetts Bureau of Substance Abuse Services [BSAS]. These funds are used to finance costs for clients without other means to pay for treatment.) One of the main enhancements of what came to be called the Boston Office of Treatment Improvement (BOTI) was the establishment of three central intake units, where clients were assessed and referred to appropriate treatment programs. For clients presenting at the central intake units and in need of detox, alternatives were referral to a residential detox program or an outpatient acupuncture program.

The Boston publicly funded treatment system has four free-standing short-term residential detox programs, with an average length of inpatient stay of 1 week, and three outpatient acupuncture detox programs, with an average duration of treatment of about 4 months. The residential detox programs offer medical detox, individual and group counseling, education, introduction to self-help groups, and referrals to appropriate postdetox inpatient or outpatient treatment, which may last up to a year for clients entering these programs. The acupuncture programs follow the National Acupuncture Detoxification Association (NADA) guidelines (Brumbaugh, 1994). During the first 2 weeks, where the focus is on acute detox, standard acupuncture with auricular points is given daily. Following acute detox, there is a maintenance period in which acupuncture is given two to three times per week for several months. During this period, body points may be added, depending on client signs and symptoms. An important component of the programs is motivational counseling, provided either individually or in group settings.

As part of BOTI, a city-wide management information system (MIS) was established that allowed tracking of clients as they moved through the treatment system. By merging Boston data with data from the BSAS MIS, we were able to track admissions to all Massachusetts programs. We closed the analytical database created

from the MIS at the end of March, 1995. In order to have 6 months of postdischarge follow-up data on each client, the population for this study was defined as cases that had been discharged from a residential detox program or an outpatient acupuncture program during the period January 1993 through September 1994. (Though one does not usually think of "discharge" from outpatient treatment, in fact a formal discharge form is required by the State for clients treated at publicly funded programs. "Discharge" does not imply clients "completed" treatment, only that they were no longer formally in the treatment program.) Each client was classified as a residential case or an acupuncture case based on the modality of their first discharge during the study period. The admission to this first modality is referred to as the *index* admission.

Data

The BOTI MIS collects admission and discharge information on each client, using the same standardized forms as the Massachusetts BSAS (Camp, Krakow, McCarty, & Argeriou, 1992). Variables recorded at admission that were used as covariates in multivariate models included: gender, race/ethnicity, age, education, employment status, yearly income, insurance, living situation (with child, with other adult but no child, alone), residence (street/shelter, institution/boarding house, private residence), prior mental health treatment (yes/no), primary drug (alcohol, cocaine, crack, heroin, and marijuana), and prior substance abuse treatment history (for different modalities, coded yes/no based on lifetime use). We created two additional variables for each client from the MIS admission data: (1) number of admissions to each modality in the year preceding each index admission (determined from the MIS by linking admission records on the same client and coded as 0, 1, ≥ 2); and (2) a drug severity score. As described in Schwartz, Mulvey, Woods, Brannigan, & Plough (1997), the drug severity score was developed by assigning points to responses to the following three questions on the admission form: age at first use, time of last use, and frequency of last use. The score was calculated by summing up points assigned to responses for each major drug used (alcohol, cocaine, crack, heroin, and marijuana).

Outcome Measures

Our outcome measure was whether clients were readmitted for detox, either residential or acupuncture, during the first 6-month period at which they were at risk for relapse. Clients in residential treatment are not at risk of relapse until they have been discharged from the program. Hence, for the residential detox programs, we measured 6-month readmission from the time of discharge from the program. Acupuncture is an outpatient program, and cli-

ents are at constant risk of relapse. Hence, for acupuncture programs, we measured 6-month detox readmission from admission to the program.

Statistical Analysis

Most baseline variables and the outcome variables were categorical. Chi-square tests were used to examine the statistical significance of differences in baseline variables between acupuncture and residential cases and to analyze differences in readmission rates. When the baseline variables were continuous (e.g., the drug severity score), *t*-tests were used.

To adjust for differences in baseline characteristics that impacted outcome, we used a stepwise procedure to build a multivariate logistic regression model predicting the log odds of detox readmission as a function of statistically significant baseline variables (at a .05 level of significance). An indicator variable, coded as one if the case was discharged from acupuncture and zero if from residential detox (the reference group) was included in the model. Our main interest was in the odds ratio (OR) associated with this indicator variable. Also, we constructed separate stepwise logistic regression models stratifying on clients' recent detox history, a variable that turned out to be strongly related to our outcome measure, and models stratifying on primary drug. We report the *c* statistic, a standard summary measure of model performance when predicting a dichotomous outcome variable (Ash & Schwartz, 1997; Harrell, Lee, Califf, Pryor, & Rosati, 1984). Among all possible pairs of clients in which one was readmitted to detox within 6 months and one was not, the *c* statistic is equivalent to the proportion of pairs in which the predicted probability of readmission was higher for the client who was readmitted than for the client who was not.

As will become apparent, acupuncture clients differed from residential detox clients in terms of many of the covariates, giving rise to the concern that multivariate models might not be able to adequately adjust for differences. To examine this possibility, we identified a subsample of acupuncture and residential detox clients that were similar in terms of baseline characteristics and reran the multivariate analysis on this subsample. To identify the subsample, we used the "propensity score" approach (Rosenbaum & Rubin, 1984), as follows: (a) stepwise logistic regression was used to build a model to predict the probability that a case was treated with acupuncture based on client baseline characteristics; (b) the predicted probabilities of acupuncture for those clients receiving acupuncture were ranked and then divided into 20 categories, such that an equal number of cases fell into each "predicted probability of acupuncture" category; (c) for each of the "predicted probability of acupuncture" categories, the number of residential detox cases whose "predicted probability of acupuncture" fell in that category was determined; and

(d) a matched sample of residential detox cases (matched on the "predicted probability of acupuncture") was selected by random sampling within each predicted-probability category of a number of residential detox cases equal to the number of acupuncture cases in that category (or, in the higher predicted probability categories where there were not sufficient residential detox cases, we randomly sampled from the group of acupuncture cases a number equal to available residential detox cases). The result of this process was a subsample of acupuncture and residential detox cases that were similar in terms of their predicted probability of receiving acupuncture. A conditional logistic regression model (Breslow & Day, 1980) (used to reflect the fact we sampled cases by strata of propensity score) was used to predict detox readmission for this subsample of cases. Independent variables in this analysis were the indicator variable for acupuncture use and the variables for recent detox history (zero, one, or two, or more residential or acupuncture detox admissions in the preceding year).

RESULTS

Baseline Characteristics

Of 8,011 clients discharged from detox during the study period, 6,907 (86%) had their first detox discharge from a residential program and 1,104 (14%) from an acupuncture program. Table 1 compares baseline characteristics of clients discharged from the two treatment modalities. Among the notable differences, acupuncture clients were more likely to have graduated college (13% vs. 4%), to be employed (57% vs. 13%), to have private insurance (15% vs. 3%), to be living with a child or adult (76% vs. 55%), and to have had prior mental health treatment (28% vs. 12%). They were less likely to live in a shelter (3% vs. 30%). Acupuncture clients' drug usage profile differed somewhat from residential detox clients, consisting of a lower percentage of clients whose primary drug was alcohol or heroin, and a somewhat larger percentage whose primary drug was crack or marijuana. The

TABLE 1
Percentage of Residential Detox and Acupuncture Clients with the Indicated Characteristic

Characteristic	% Residential Detox (n = 6,907)	% Acupuncture (n = 1,104)	p
Gender (female)	29.1	33.0	.01
Race/ethnicity			
Black	45.7	46.2	.74
Hispanic	11.7	9.7	.05
White	40.9	43.0	.19
Education			
High school graduate	55.9	59.4	.03
College graduate	3.9	13.4	<.01
Employment (unemployed)	86.8	43.2	<.01
Insurance			
Uninsured	65.4	52.3	<.01
Medicaid	28.2	21.2	<.01
Private insurance	3.0	15.4	<.01
Lives with			
Child	9.5	19.3	<.01
Adult (no child)	45.5	56.5	<.01
In shelter	30.3	2.9	<.01
In institution	4.0	6.1	<.01
Prior mental health treatment	12.3	27.8	<.01
Primary drug			
Alcohol	42.3	32.4	<.01
Cocaine	16.2	16.6	.78
Crack	15.9	20.2	<.01
Heroin	24.6	19.0	<.01
Marijuana	0.7	8.4	<.01
Substance abuse admissions in the last year			
Residential detox			
None	56.7	81.0	<.01
1	20.2	12.1	<.01
≥2	23.1	7.0	<.01
Short-term residential (none)	76.2	94.8	<.01
Long-term residential (none)	80.5	93.5	<.01
Outpatient (none)	80.6	54.3	<.01
Acupuncture (none)	95.9	90.1	<.01

average drug severity score was similar in the two groups, 27.6 for acupuncture clients and 27.4 for residential detox clients ($p = .65$).

There were large differences in prior use of the substance abuse treatment system. In the year preceding their index admission, acupuncture clients were much less likely than residential detox clients to have had admissions to residential programs: 19% versus 43% to residential detox, 5% versus 24% to short-term (30-day) treatment, 6% versus 19% to long-term treatment. However, they were more likely to have had an outpatient (nonacupuncture) treatment admission in the last year (46% vs. 19%).

Outcomes

Eighteen percent of acupuncture clients were readmitted to detox within 6 months, much lower than the 36% of residential detox clients who were readmitted within 6 months of discharge. However, after adjusting for differences in baseline characteristics, the odds that an acupuncture client was readmitted to detox in 6 months were 0.71 of the odds that a residential detox client was readmitted ($p = .02$, 95% Confidence Interval [CI] = 0.53–0.95).

The c statistic for the model was 0.96. In addition to the "prior detox treatment in the last year" variables, the other statistically significant variables to enter the model were the following: black (OR = 0.76), high school graduate only (OR = 1.27), drug severity score (OR = 1.01), admission following intake at a central intake site (OR = 1.28) and one admission to a short-term (30-day) residential treatment program in the last year (OR = 0.79). However, number of detox admissions in the year preceding the index admission were the only really important variables in the model: one detox admission in the last year, OR = 412; two or more detox admissions, OR = 1723. In a model including only the recent detox history variables (zero, one, or two, or more detox ad-

missions in the year preceding the index admission), the c statistic was 0.95, indicating the extent to which recent detox history was the main factor accounting for detox readmission rates.

The reason for the very high OR associated with recent detox admissions is illustrated in Table 2. Clients without a detox admission in the last year were very unlikely to be readmitted for detox in 6 months, whatever their mode of treatment; clients with two or more detox admissions in the last year were very likely to be readmitted, whatever their mode of treatment.

Table 2 also shows results when stratifying on recent detox history. Acupuncture appears particularly beneficial for those clients with two or more detox admissions in the year preceding their index admission. There is weak evidence ($p = 0.15$) that residential treatment might be the preferred modality for those with a single detox admission in the preceding year. As shown in Table 3, acupuncture appears particularly effective for clients whose primary substance was alcohol. Acupuncture and residential adjusted readmission rates (to take into account differences in statistically significant baseline variables) were similar for the other drugs.

Based on results of the stepwise logistic regression model developed to predict the probability of acupuncture, the average predicted probability of receiving acupuncture among clients actually getting acupuncture was .50; the average predicted probability of receiving acupuncture among clients in residential detox was .07. These differences reflect baseline differences between the two groups of clients. The c statistic associated with this model was 0.90. We were able to match 740 acupuncture clients with suitable residential detox clients (in the higher "predicted probability of acupuncture" categories there were not sufficient residential detox cases).

The subsamples selected through stratified sampling based on propensity score category were quite similar in terms of the covariates. For example, listed by percent-

TABLE 2
Percentage of Clients Readmitted to Residential Detox or Acupuncture Within 6 Months and Odds Ratio Associated with Acupuncture as a Function of Number of Detox Admissions in the Year Preceding Index Admission

Admissions in Year Preceding Index Admission	Residential Detox		Acupuncture Detox		Multivariate Model Odds Ratio
	<i>n</i>	% Readmitted	<i>n</i>	% Readmitted	
No acupuncture admissions and no residential detox admissions	3,781	0.0	821	0.0 (.64) ^a	— ^b
1 residential detox admission	1,326	65.6	113	72.6 (.13)	1.37 (0.89–2.12) ^c
≥2 residential detox admissions	1,518	89.4	61	78.7 (.01)	0.47 (0.25–0.88)
No residential detox admissions and 1 acupuncture admission	124	78.2	69	40.6 (<.01)	—

^aNumbers in parentheses are the p values for a test of the null hypothesis that readmission rates of residential detox and acupuncture clients are similar.

^bToo few readmission cases to develop a model.

^cOdds ratio (acupuncture clients compared to the reference group of residential detox clients) and 95% confidence interval for the odds ratio.

TABLE 3
Percentage of Clients Readmitted to Residential Detox or Acupuncture Within 6 Months and the Multivariate Model Odds Ratio Associated with Acupuncture Readmission as a Function of Primary Drug

Primary drug	Residential Detox		Acupuncture		Multivariate Model Odds Ratio ^a
	<i>n</i>	% Readmitted	<i>n</i>	% Readmitted	
Alcohol	2,919	37.3	358	10.9	0.53 (0.29–0.98)
Cocaine	1,122	31.0	183	19.7	1.03 (0.52–2.04)
Crack	1,099	28.8	223	21.5	0.97 (0.54–1.74)
Heroin	1,699	40.6	210	31.4	1.11 (0.63–1.96)

^aOdds ratio associated with acupuncture admission (95% confidence interval).

age of acupuncture clients and then percentage of residential detox clients, clients in the two subsamples were much more equivalent (compared to the differences in Table 1) in terms of having graduated college (7% in both cases), being employed (42% vs. 41%), having private insurance (6% vs. 9%), living with a child or adult (77% vs. 72%), living in a shelter (4% vs. 5%), and having had prior mental health treatment (21% in both cases). They were also more equivalent in terms of their recent use of the treatment system: in the preceding year: 26% versus 27% had detox admissions, 8% versus 9% had admissions to short-term residential treatment, 9% versus 11% had admissions to long-term residential treatment, and 37% versus 39% were in outpatient treatment. Finally, they were more similar in terms of primary drug: alcohol (30% vs. 35%), cocaine (18% in both cases), crack (23% in both cases), heroin (23% vs. 21%), and marijuana (3% in both cases).

When the logistic regression model was run on the subsample of matched cases, the coefficient associated with acupuncture indicated that the odds of an acupuncture case being readmitted to detox in 6 months were 0.61 of the odds of a residential case being readmitted (95% CI 0.39–0.94).

DISCUSSION

Acupuncture appears as an effective modality for at least some clients seeking substance abuse detox. The 14% of clients that used acupuncture had lower 6-month detox readmission rates, even after taking into consideration ways in which they differed from clients admitted to residential detox programs. The propensity score analysis suggests that for at least another 10% or so of those in residential treatment (740/6,907), acupuncture would have been an effective alternative. Acupuncture appears particularly effective for those clients whose primary substance was alcohol and for those with two or more detox admissions in the year preceding their index admission.

In terms of our drug severity score, acupuncture clients were similar to residential detox clients. However, it is important to note that our measure of drug severity was used only as a measure of relative severity among clients within the Boston system, and its external validity has not been analyzed. We did collect severity information using the Addiction Severity Index (ASI) (McLellan, Luborsky, O'Brien, & Woody, 1980; McLellan et al., 1988; McLellan et al., 1992) on a convenience sample of about 830 residential detox clients and 560 acupuncture clients at the central intake sites. The ASI measures severity along the following dimensions: medical, employment, alcohol, drugs, legal, family/social, and psychological/emotional. The only statistically significant difference in either severity scores (which are based on both objective client responses and subjective interviewer assessment) or composite scores (which are calculated solely from client responses), was the greater severity score for acupuncture clients along the psychological dimension. There were no differences in either alcohol severity or drug severity between the two groups, supporting the findings when our severity score was used. It is interesting to note that the group of acupuncture clients on whom the ASI was done had 6-month readmission rates similar to the group on whom the ASI was not done ($p = .47$). The group of residential detox clients on whom the ASI was done had poorer outcomes than those on whom the ASI was not completed (20% higher predicted probability of 6-month readmission, $p < .001$), perhaps suggesting the small sample of ASI completers among residential detox cases was a more severe group than the general population of residential detox cases.

The extent to which outcomes depended on recent detox history is discouraging. Those clients who had not been admitted for detox within a year of their index admission were very unlikely to be readmitted to detox within 6 months, whatever their treatment. Those who had been admitted for detox in the last year had much higher readmission rates. Thus, it really matters less how the person is treated than what the client's recent history is. This may reflect the particular population studied, an urban poor

population utilizing the publicly funded treatment system, and the chronic, relapsing nature of the disease.

It is interesting to note that once account is taken of the number of detox admissions in the last year, primary drug does not have a statistically significant impact on the likelihood of detox readmission. The effect of the different relapse rates associated with different primary substances is captured by recent relapse history.

Though an acupuncture session is much less expensive than a day in a residential detox program, the longer duration of treatment reduces the potential economic benefit. We do not know "true" costs of acupuncture or residential treatment. However, based on Massachusetts reimbursement rates at the time of the study, an average residential detox stay is estimated to "cost" \$850 to \$900. The state pays \$16.77 per unit of acupuncture service, which includes a visit for both acupuncture and group counseling. With an average duration of treatment of about 17 weeks, and assuming an average of 2.5 sessions per week after the 2 week daily visits for acute detox, the cost of acupuncture to the state is about \$830, not much less than a week in residential treatment. However, a big advantage of acupuncture is that capacity can be expanded without adding inpatient services.

An obvious limitation of this study is that clients were not randomized to modality. Rather, the modality to which clients were referred reflected both clinical assessment and patient preference. Discussions with central intake coordinators suggest that, for clients judged clinically suitable for acupuncture, it was necessary to educate the clients about acupuncture before they were willing to enter this modality. Thus, particularly for those without prior exposure to acupuncture, referral to acupuncture reflected to a large extent clinical judgment about appropriateness, followed by successful patient education about the potential value of acupuncture.

The other major limitation of the study is with our outcome measure, readmission to detox. Though one would obviously like data on pre- and post-drug and alcohol usage, our measure is not unreasonable. For example, it has been shown that among homeless substance abusers, there were significant differences in ASI scores in five of the seven ASI dimensions among those readmitted for detox versus those who were not (Argeriou, McCarty, Mulvey, & Daley, 1994). This lends validity to the use of detox readmission as an outcome measure. Further, our outcome measure was useful in a study of the role of case management in substance abuse treatment (Shwartz, Baker, Mulvey, & Plough, 1997). And, readmission for substance abuse treatment has been used as an outcome measure in a study of the performance of inpatient substance abuse treatment programs in the Veterans Administration (Barnett & Swindle, 1997; Peterson, Swindle, Phibbs, Recine, & Moos, 1994). Although detox readmission is not synonymous with relapse, there is no a priori reason to expect that acupuncture versus residential detox clients might differentially seek detox

admission when they relapse. Thus, lack of data on actual relapse rates is not likely to seriously bias our results.

As noted in the introduction, our study is of the value of outpatient detox programs that utilize acupuncture; it is not of the contribution that acupuncture makes to the outcomes associated with these programs. Though more focused observational studies and randomized trials are clearly needed, our study does suggest the value of outpatient acupuncture detox programs as a component of a substance abuse treatment system. This modality is particularly useful when residential detox beds are in short supply, for it allows some of the demand for detox to be met on an outpatient basis.

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Clinton Presidential Records

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Responses to the White House Commission on Complementary and Alternative Medicine Policy

Tuesday, December 5, 2000

**Session VI: CAM Integration in Delivery Systems
2:30 - 4:30 p.m.**

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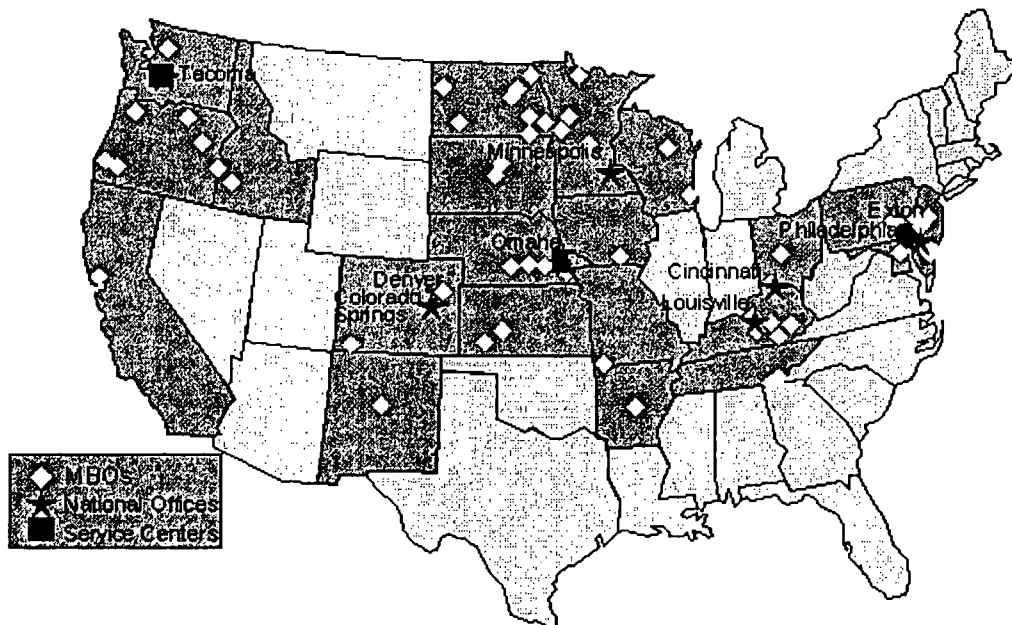
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by Milt Hammerly, MD

on behalf of Catholic Health Initiatives (CHI)

Catholic Health Initiatives (CHI) Executive Summary

CHI is unique among health care systems in the United States. CHI was formed in 1996 and is sponsored by 12 congregations of women religious with a rich history of serving the health care needs of diverse communities. Governance by the board of stewardship trustees is by design an equal religious-lay partnership. CHI is one of the largest not-for-profit health care systems in the country with approximately 75,000 employees and annual operating revenues of \$5 billion. CHI operates 69 hospitals and 49 long-term care, assisted living facilities in 22 states and 72 communities ranging from rural to urban.



10 LARGEST NOT-FOR-PROFIT HEALTHCARE SYSTEMS

By staffed U.S. acute-care beds

	Beds		Hospitals	
	1999	1998	1999	1998
U.S. Department of Veterans Affairs	21,583	23,176	172	172
Ascension Health ¹	12,705	—	60	—
Catholic Health Initiatives	10,023	11,877	69	65
Christus Health ²	9,600	—	27	—
Catholic Health East	8,835	8,877	32	31
Catholic Healthcare West	8,172	6,419	48	36
Mercy Health Services	6,944	6,965	17	17
Sutter Health	5,817	5,398	25	24
New York Presbyterian Healthcare System ³	5,282	5,282	16	16
Catholic Healthcare Partners	5,221	3,698	27	22

¹ In November 1999, Daughters of Charity National Health System, St. Louis, and Sisters of St. Joseph Health System, Ann Arbor, Mich., merged to form Ascension Health, St. Louis.

² Christus Health was formed through the merger of Sisters of Charity, Houston, and Incarnate Word Health System, San Antonio.

³ Previously known as New York Presbyterian Healthcare Network.

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The organization is committed to creating new models of health care, based on collaborative relationships and partnerships with community groups, agencies and other health care organizations. The hallmark of CHI is its Mission and Ministry Fund that devotes financial resources to improve the health of communities served by its facilities. Through this national healthy communities commitment, hospitals and health care facilities throughout the organization are developing unique programs to address the root causes of serious social and health issues - and create solutions for the long term.

More detailed information about CHI is available at the following website:
www.catholichealthinit.org

Further information about CHI is also available from the national corporate office:

Catholic Health Initiatives
1999 Broadway
Suite 2600
Denver, CO 80202

Phone: 303-298-9100
Fax: 303-298-9690



A spirit of innovation, a legacy of care.

Question 1: Description of CAM or Integrative Health Care Programs at CHI